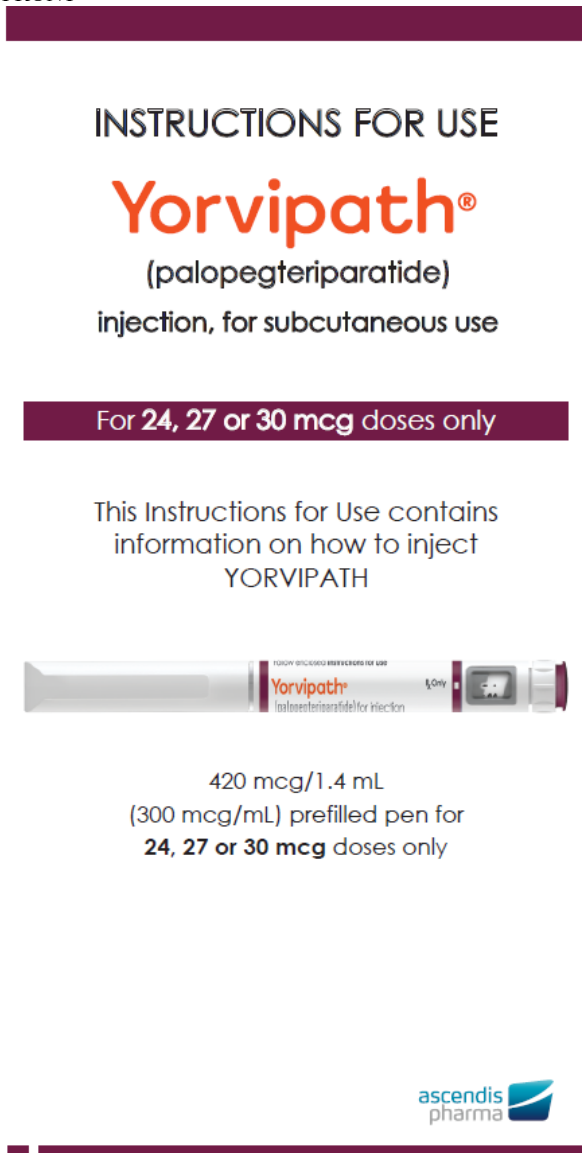



Label	Content
<p>FRONT</p>  <p><b>INSTRUCTIONS FOR USE</b></p> <p><b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p><b>For 24, 27 or 30 mcg doses only</b></p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p>  <p>420 mcg/1.4 mL (300 mcg/mL) prefilled pen for <b>24, 27 or 30 mcg</b> doses only</p> <p>ascendis pharma</p>	<p><b>INSTRUCTIONS FOR USE</b></p> <p><b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p>For <b>24, 27 or 30 mcg</b> doses only</p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p> <p>420 mcg/1.4 mL (300 mcg/mL) prefilled pen for <b>24, 27 or 30 mcg</b> doses only</p> <p>ascendis pharma</p>
<p>Back</p>	<p><b>Additional information</b></p> <p>If you need help, please ask your health care provider or nurse for advice or contact the Ascendis Pharma Helpline: <b>Ascendis Pharma Helpline:</b> Toll-free telephone number: 1-844-442-7236</p> <p>Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12 DK-2900 Hellerup Denmark</p> <p>ascendis pharma</p>

#### Additional information

If you need help, please ask your health care provider or nurse for advice or contact the Ascendis Pharma Helpline:

127149

#### Ascendis Pharma Helpline:

Toll-free telephone number:  
1-844-442-7236

Ascendis Pharma Bone Diseases A/S  
Tuborg Boulevard 12  
DK-2900 Hellerup  
Denmark



Panel 1

#### Troubleshooting

##### 1. How often must I test the pen flow?

You should only test the pen flow (Section 2) the first time you use a new pen (or if you think it might be damaged) to not waste medicine. The test checks to make sure the medicine flows through the pen so that you get the right doses of medicine.

##### 2. I do not see drops appear after I have tested the pen flow 5 times. What should I do?

If you see no drop on the needle tip after **5 attempts** it might be because there is no flow through the pen and needle.  
Change the needle (see Section 5, Step 13) and test the pen flow again (see Section 2, Steps A-C). You can be sure the flow works correctly when you see the drop of medicine.  
If it still does not work, throw away (discard) the pen and contact your health care provider.

##### 3. How do I know I have completed

## Troubleshooting

### 1. How often must I test the pen flow?

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### 3. How do I know I have completed the injection?

Your injection is only completed after you have pressed the push button all the way in and the dose selector has rotated back to the "0" and you have kept the needle in the skin for 5 seconds.

### 4. Why do I have to keep holding the pen in the skin for 5 seconds?

Some medicine might flow back into the pen or flow backward from the injection site and be left on the skin. Holding the pen in the skin for 5 seconds helps to make sure that all the medicine has been injected.

### 5. I cannot dial the dose selector to the required dose. What should I do?

The pen does not allow a larger dose to be set than what is left in the pen. If your dose is larger than the amount of medicine left in the pen you will not be able to dial a full dose. You must throw away your pen and take the full dose of medicine with a new pen.

### 6. The red lock covers the needle before I start injection. What should I do?

Unscrew and throw away the needle in use (see Section 5, Step 13). Take a new needle from the box and start again from Step 1. Every box contains an extra needle.

### the injection?

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Unscrew and throw away the needle in use (see Section 5, Step 13). Take a new needle from the box and start again from Step 1. Every box contains an extra needle.

Panel 2

## Storing Your Pen

- **Until first use**, refrigerate your pens between 2°C to 8°C (36°F to 46°F) and keep in the package to protect from light.
- **After first use**, store your pen for 14 days at room temperature below 30°C (86°F).
- **Do not** leave your pen in a car or another place where it can get too hot or too cold.
- **Do not** freeze your pen.
- Store YORVIPATH away from heat.
- **Keep the YORVIPATH pen out of the reach of children.**

Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.

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Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.

Panel 3

## Caring For Your Pen

- Handle your pen with care.
- Keep your pen dry.
- Use a moist cloth to clean your pen.
- **Do not** drop or knock your pen against hard surfaces. If you do, test the pen flow again (Section 2, Steps A – C) before next use.
- **Do not** apply extra force to your pen. It might be empty, damaged and no longer works properly.
- **Do not** attempt to repair a damaged pen yourself. If your pen is damaged, contact the Ascendis Pharma Helpline.

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Panel 4

## Important Information You Need To Know Before Using Your YORVIPATH Pen

Read and follow this Instructions for Use carefully so that you inject YORVIPATH the right way.

If you do not understand or are unable to complete a step that is described in this Instructions for Use, contact your health care provider or nurse or the Ascendis Pharma Helpline.

Make sure you have received training from your health care provider or nurse before injecting. This is important to make sure that you get the correct treatment.

Inject YORVIPATH into the belly (abdomen) or in the front of the thigh. Your pen can deliver doses of **24, 27, or 30 mcg**. It is used for injections under the skin (subcutaneous) for daily treatment of hypoparathyroidism. Your pen is a prefilled dial-a-dose throw away (disposable) pen.

It contains medicine for **14 days of use** and is intended to be used **1 time** each day. Do not use more than one injection to achieve the recommended once daily dosage.

You can dial doses of **24, 27 or 30 mcg** with the pen.

### For Correct Use

If you are blind or visually impaired or if you have lack of concentration **do not** use your pen without help. Get help from a person who is trained to use the YORVIPATH pen.

Store your pen out of the reach of children and any other persons who do not know how to handle it properly.

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Panel 5

- Only use your pen as directed by your health care provider or nurse.
- The pen and needles are for single-patient use only. Do not share your pen or needles with other people. It might lead to infection (cross-contamination).
- Start by checking your pen to make sure it is the correct pen.
- Always check the expiration date on the pen label and needle foil before use.
- Always inspect the pen visually before use to make sure it is not damaged and medicine is clear, colorless and without particles.
- Always use a new needle for each injection.
- Only inject into the abdomen or front of thigh as instructed by your health care provider or nurse.

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Panel 6

## Compatible Pen Needles

In each of the **two** inner boxes there are **15** disposable Clickfine® AutoProtect™ Needles (31G x 5mm) together with a YORVIPATH prefilled pen for doses of 24, 27 or 30 mcg. Always use the needles that come with YORVIPATH pen for your injections.

## For Correct Disposal

Always put your used YORVIPATH needles in an FDA-cleared sharps disposal container **right away after use**.

Always put your used pen in an FDA-cleared sharps disposal container **after 14 days of use**.

Do not throw away (dispose of) YORVIPATH in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic.
- can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
- upright and stable during use.
- leak-resistant.
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>. Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

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Label	Content
<p>Panel 7</p> <div data-bbox="204 331 842 990"> <h3>Parts Overview</h3> <p><b>Figure A</b></p> <p><b>Note:</b> There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p><b>Figure B</b></p> <p>Sharps disposal container Alcohol wipe</p> </div>	<h3>Parts Overview</h3> <p><b>Figure A</b> <b>Symbols:</b></p> <ul style="list-style-type: none"> <li>-Droplets</li> <li>-Doses (24, 27 or 30 mcg)</li> <li>-End-of-dose</li> <li>-Pen cap</li> <li>-Inspection window (medicine inside)</li> <li>-Pen</li> <li>-Pen label</li> <li>-Push button</li> <li>-Dose selector</li> <li>-Dose window</li> <li>-Needle cover</li> <li>-Needle tip</li> <li>-Blue sleeve</li> <li>-Needle</li> <li>-Foil</li> </ul> <p><b>Single Use Safety Needle:</b></p> <p><b>Note:</b> There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p><b>Figure B</b></p> <p>Sharps disposal container Alcohol wipe</p>
<p>Panel 8</p> <div data-bbox="204 1048 842 1684"> <h3>1 Prepare Pen And Needle</h3> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the <b>expiration date</b> on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Figure C</b></p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it <b>do not</b> use the pen. Use a new pen.</p> <p><b>Figure D</b></p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used 1 time and locks after use.</p> <p><b>Figure E</b></p> <p><b>Step 4</b> Click the needle straight onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Figure F</b></p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p> <p><b>Figure G</b></p> </div>	<p>1 <b>Prepare Pen And Needle</b></p> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the <b>expiration date</b> on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Figure C</b> Expiration date OK?</p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it <b>do not</b> use the pen. Use a new pen.</p> <p><b>Figure D</b> Medicine OK?</p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used 1 time and locks after use.</p> <p><b>Figure E</b></p> <p><b>Step 4</b> Click the needle <b>straight</b> onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Figure F</b> Click!</p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p>







<p>Panel 9</p> <div data-bbox="204 255 836 913"> <h2>2 If New Pen, Test Pen Flow</h2> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H).</p> <p><b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Figure H</b></p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up.</p> <p><b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Figure I</b></p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the dose selector rotates back to the symbol "••" (see Figure J).</p> <p><b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> <p><b>Figure J</b></p> </div>	<p><b>Figure G</b></p> <p>2 <b>If New Pen, Test Pen Flow</b> Day 1</p> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H). <b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Figure H</b></p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up. <b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Figure I</b> tap tap</p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the selector rotates back to the symbol "••" (see Figure J). <b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> <p><b>Figure J</b></p>
<p>Panel 10</p> <div data-bbox="204 1178 836 1818"> <h2>3 Prepare Injection and Select Dose</h2> <p><b>Step 6</b> Choose injection site. There are <b>two</b> regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b></p> <p><b>Stomach (Abdomen)</b> at least 2 inches away from the belly button</p> <p><b>Thighs</b></p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b></p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (24, 27 or 30 mcg) by turning the dose selector clockwise (to the right) (see Figure M).</p> <p><b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> <p><b>Figure M</b></p> </div>	<p>3 <b>Prepare Injection and Select Dose</b></p> <p><b>Step 6</b> Choose injection site. There are <b>two</b> regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b> Front <b>Stomach (Abdomen)</b> at least 2 inches away from the belly button <b>Thighs</b></p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b> Use alcohol wipe</p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (24, 27 or 30 mcg) by turning the dose selector clockwise (to the right) (see Figure M). <b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> <p><b>Figure M</b></p>

Panel 11

## 4 Inject Dose

**Attention** Use the injection technique recommended by your health care provider or nurse. Read this whole section (Steps 9 - 12) before you start to inject.

<p><b>Step 9</b> Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).</p>	<p>Figure N</p> 
<p><b>Step 10</b> Push the pen straight towards the skin until you hear a click and the blue sleeve can no longer be seen (see Figure O).</p>	<p>Figure O</p> 
<p><b>Step 11</b> Press the push button all the way in and hold steady for 5 seconds. Make sure the dose selector rotates back to the symbol "●". This means that you have given the full dose (see Figure P).</p>	<p>Figure P</p> 
<p><b>Step 12</b> Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).</p>	<p>Figure Q</p> 

4

## Inject Dose

### Attention

Use the injection technique recommended by your health care provider or nurse.

Read this whole section (Steps 9 - 12) before you start to inject.

### Step 9

Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).

### Figure N

### Step 10

Push the pen straight towards the skin until you hear a click and the blue sleeve can no longer be seen (see Figure O).

### Figure O

Click!

### Step 11

Press the push button all the way in and hold steady for 5 seconds. Make sure the dose selector rotates back to the symbol "●". This means that you have given the full dose (see Figure P).

### Figure P

Press...then hold 5 seconds.



### Step 12

Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).

### Figure Q

Panel 12

## 5 Throw Away Used Needle

<p><b>Step 13</b> Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). Do not attempt to recap the needle. You could poke yourself on the back end.</p>	<p>Figure R</p> 
<p><b>Step 14</b> Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).</p>	<p>Figure S</p> 

5

## Throw Away Used Needle

### Step 13

Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). **Do not** attempt to recap the needle. You could poke yourself on the back end.

### Figure R

### Step 14

Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).

### Figure S

click!

Panel 13

## 6 Throw Away Used Pen

**Important:** Always throw away the pen 14 days after first use according to local regulations.

Always throw away your pen and any extra needles after 14 days of use, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.



6


## Throw Away Used Pen

Day 14

**Important:** Always throw away the pen 14 days after first use according to local regulations.

Always throw away your pen and any extra needles after 14 days of use, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.

### Figure T

Label	Content
<p>FRONT</p> <p><b>INSTRUCTIONS FOR USE</b></p> <p><b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p>For <b>15, 18 or 21 mcg</b> doses only</p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p>  <p>294 mcg/0.98 mL (300 mcg/mL) prefilled pen for <b>15, 18 or 21 mcg</b> doses only</p> <p>ascendis pharma</p>	<p><b>INSTRUCTIONS FOR USE</b></p> <p><b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p>For <b>15, 18 or 21 mcg</b> doses only</p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p> <p>294 mcg/0.98 mL (300 mcg/mL) prefilled pen for <b>15, 18 or 21 mcg</b> doses only</p> <p>ascendis pharma</p>
<p>Back</p>	<p><b>Additional information</b></p> <p>If you need help, please ask your health care provider or nurse for advice or contact the Ascendis Pharma Helpline:</p> <p><b>Ascendis Pharma Helpline:</b> Toll-free telephone number: 1-844-442-7236</p> <p>Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12 DK-2900 Hellerup Denmark</p> <p>ascendis pharma</p>

#### Additional information

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127148

#### Ascendis Pharma Helpline:

Toll-free telephone number:  
1-844-442-7236

Ascendis Pharma Bone Diseases A/S  
Tuborg Boulevard 12  
DK-2900 Hellerup  
Denmark



Panel 1

#### Troubleshooting

##### 1. How often must I test the pen flow?

You should only test the pen flow (Section 2) the first time you use a new pen (or if you think it might be damaged) to not waste medicine. The test checks to make sure the medicine flows through the pen so that you get the right doses of medicine.

##### 2. I do not see drops appear after I have tested the pen flow 5 times. What should I do?

If you see no drop on the needle tip after **5 attempts** it might be because there is no flow through the pen and needle.  
Change the needle (see Section 5, Step 13) and test the pen flow again (see Section 2, Steps A-C). You can be sure the flow works correctly when you see the drop of medicine.  
If it still does not work, throw away (discard) the pen and contact your health care provider.

##### 3. How do I know I have completed the injection?

Your injection is only completed after

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If you see no drop on the needle tip after 5 attempts it might be because there is no flow through the pen and needle.

Change the needle (see Section 5, Step 13) and test the pen flow again (see Section 2, Steps A-C). You can be sure the flow works correctly when you see the drop of medicine.

If it still does not work, throw away (discard) the pen and contact your health care provider.

### 3. How do I know I have completed the injection?

Your injection is only completed after you have pressed the push button all the way in and the dose selector has rotated back to the "•" and you have kept the needle in the skin for 5 seconds.

### 4. Why do I have to keep holding the pen in the skin for 5 seconds?

Some medicine might flow back into the pen or flow backward from the injection site and be left on the skin. Holding the pen in the skin for 5 seconds helps to make sure that all the medicine has been injected.

### 5. I cannot dial the dose selector to the required dose. What should I do?

The pen does not allow a larger dose to be set than what is left in the pen. If your dose is larger than the amount of medicine left in the pen you will not be able to dial a full dose. You must throw away your pen and take the full dose of medicine with a new pen.

### 6. The red lock covers the needle before I start injection. What should I do?

Unscrew and throw away the needle in use (see Section 5, Step 13). Take a new needle from the box and start again from Step 1. Every box contains an extra needle.

you have pressed the push button all the way in and the dose selector has

rotated back to the "•" and you have kept the needle in the skin for 5 seconds.

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Unscrew and throw away the needle in use (see Section 5, Step 13). Take a new needle from the box and start again from Step 1. Every box contains an extra needle.

Panel 2

## Storing Your Pen

- **Until first use**, refrigerate your pens between 2°C to 8°C (36°F to 46°F) and keep in the package to protect from light.
- **After first use**, store your pen for 14 days at room temperature below 30°C (86°F).
- **Do not** leave your pen in a car or another place where it can get too hot or too cold.
- **Do not** freeze your pen.
- Store YORVIPATH away from heat.
- **Keep the YORVIPATH pen out of the reach of children.**

Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.

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Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.

Panel 3

## Caring For Your Pen

- Handle your pen with care.
- Keep your pen dry.
- Use a moist cloth to clean your pen.
- **Do not** drop or knock your pen against hard surfaces. If you do, test the pen flow again (Section 2, Steps A – C) before next use.
- **Do not** apply extra force to your pen. It might be empty, damaged and no longer works properly.
- **Do not** attempt to repair a damaged pen yourself. If your pen is damaged, contact the Ascendis Pharma Helpline.

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Panel 4

## Important Information You Need To Know Before Using Your YORVIPATH Pen

Read and follow this Instructions for Use carefully so that you inject YORVIPATH the right way.

If you do not understand or are unable to complete a step that is described in this Instructions for Use, contact your health care provider or nurse or the Ascendis Pharma Helpline.

Make sure you have received training from your health care provider or nurse before injecting. This is important to make sure that you get the correct treatment.

Inject YORVIPATH into the belly (abdomen) or in the front of the thigh. Your pen can deliver doses of **15, 18, or 21 mcg**. It is used for injections under the skin (subcutaneous) for daily treatment of hypoparathyroidism. Your pen is a prefilled dial-a-dose throw away (disposable) pen.

It contains medicine for **14 days of use** and is intended to be used **1 time** each day. Do not use more than one injection to achieve the recommended once daily dosage. You can dial doses of **15, 18 or 21 mcg** with the pen.

### For Correct Use

If you are blind or visually impaired or if you have lack of concentration **do not** use your pen without help. Get help from a person who is trained to use the YORVIPATH pen.

Store your pen out of the reach of children and any other persons who do not know how to handle it properly.

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Panel 5

- Only use your pen as directed by your health care provider or nurse.
- The pen and needles are for single-patient use only. Do not share your pen or needles with other people. It might lead to infection (cross-contamination).
- Start by checking your pen to make sure it is the correct pen.
- Always check the expiration date on the pen label and needle foil before use.
- Always inspect the pen visually before use to make sure it is not damaged and medicine is clear, colorless and without particles.
- Always use a new needle for each injection.
- Only inject into the abdomen or front of thigh as instructed by your health care provider or nurse. Remember to change injection site for each



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## Compatible Pen Needles

In each of the **two** inner boxes there are **15** disposable Clickfine® AutoProtect™ Needles (31G x 5mm) together with a YORVIPATH prefilled pen for doses of 15, 18 or 21 mcg. Always use the needles that come with YORVIPATH pen for your injections.

## For Correct Disposal

Always put your used YORVIPATH needles in an FDA-cleared sharps disposal container **right away after use**.

Always put your used pen in an FDA-cleared sharps disposal container **after 14 days of use**.

Do not throw away (dispose of) YORVIPATH in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic.
- can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
- upright and stable during use.
- leak-resistant.
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>. Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

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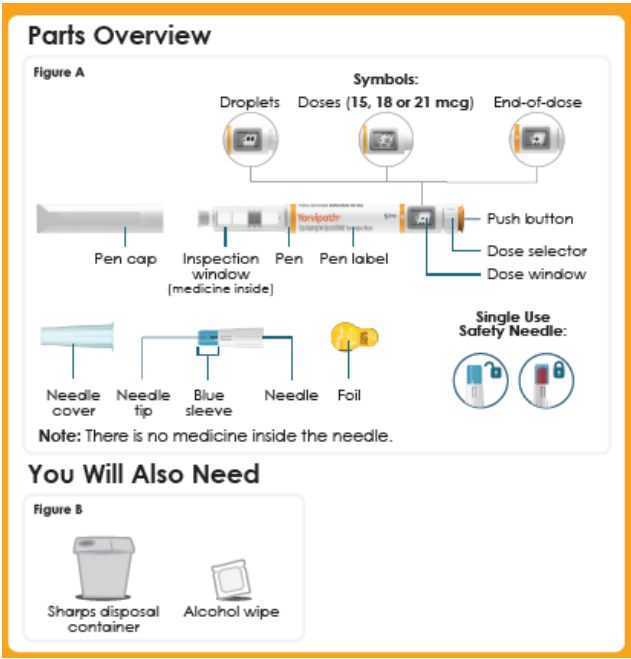
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Label	Content
<p>Panel 7</p>  <p><b>Parts Overview</b></p> <p>Figure A</p> <p>Symbols:</p> <p>Droplets Doses (15, 18 or 21 mcg) End-of-dose</p> <p>Pen cap Inspection window (medicine inside) Pen Pen label Push button Dose selector Dose window</p> <p>Needle cover Needle tip Blue sleeve Needle Foil</p> <p><b>Single Use Safety Needle:</b></p> <p>Note: There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p>Figure B</p> <p>Sharps disposal container Alcohol wipe</p>	<p><b>Parts Overview</b></p> <p><b>Figure A</b> <b>Symbols:</b></p> <ul style="list-style-type: none"> <li>-Droplets</li> <li>-Doses (15, 18 or 21 mcg)</li> <li>-End-of-dose</li> <li>-Pen cap</li> <li>-Inspection window (medicine inside)</li> <li>-Pen</li> <li>-Pen label</li> <li>-Push button</li> <li>-Dose selector</li> <li>-Dose window</li> <li>-Needle cover</li> <li>-Needle tip</li> <li>-Blue sleeve</li> <li>-Needle</li> <li>-Foil</li> </ul> <p><b>Single Use Safety Needle:</b> <b>Note:</b> There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p><b>Figure B</b> Sharps disposal container Alcohol wipe</p>
<p>Panel 8</p> <p><b>1 Prepare Pen And Needle</b></p> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the <b>expiration date</b> on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Figure C</b></p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it <b>do not</b> use the pen. Use a new pen.</p> <p><b>Figure D</b></p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used <b>1 time</b> and locks after use.</p> <p><b>Figure E</b></p> <p><b>Step 4</b> Click the needle <b>straight</b> onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Figure F</b></p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p> <p><b>Figure G</b></p>	<p>1 <b>Prepare Pen And Needle</b></p> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the <b>expiration date</b> on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Figure C</b> Expiration date OK?</p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it <b>do not</b> use the pen. Use a new pen.</p> <p><b>Figure D</b> Medicine OK?</p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used <b>1 time</b> and locks after use.</p> <p><b>Figure E</b></p> <p><b>Step 4</b> Click the needle <b>straight</b> onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Figure F</b> Click!</p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p>

<p>Panel 9</p> <div data-bbox="204 255 834 913"> <h2>2 If New Pen, Test Pen Flow</h2> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H).</p> <p><b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up.</p> <p><b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the dose selector rotates back to the symbol "••" (see Figure J).</p> <p><b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> </div>	<p><b>Figure G</b></p> <p>2 If New Pen, Test Pen Flow Day 1</p> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H). <b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Figure H</b></p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up. <b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Figure I</b> tap tap</p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the selector rotates back to the symbol "••" (see Figure J). <b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> <p><b>Figure J</b></p>
<p>Panel 10</p> <div data-bbox="204 1182 834 1818"> <h2>3 Prepare Injection and Select Dose</h2> <p><b>Step 6</b> Choose injection site. There are two regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b> Stomach (Abdomen) at least 2 inches away from the belly button Thighs</p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b> Use alcohol wipe</p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (15, 18 or 21 mcg) by turning the dose selector clockwise (to the right) (see Figure M).</p> <p><b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> </div>	<p>3 Prepare Injection and Select Dose</p> <p><b>Step 6</b> Choose injection site. There are two regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b> Front Stomach (Abdomen) at least 2 inches away from the belly button Thighs</p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b> Use alcohol wipe</p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (15, 18 or 21 mcg) by turning the dose selector clockwise (to the right) (see Figure M). <b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> <p><b>Figure M</b></p>

Panel 11

4

Inject Dose

Attention

Use the injection technique recommended by your health care provider or nurse. Read this whole section (Steps 9 - 12) before you start to inject.

Step 9

Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).

Figure N

Step 10

Push the pen straight towards the skin until you hear a click and the blue sleeve can no longer be seen (see Figure O).

Figure O

Step 11

Press the push button all the way in and hold steady for 5 seconds. Make sure the dose selector rotates back to the symbol "•". This means that you have given the full dose (see Figure P).

Figure P

Step 12

Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).

Figure Q

4

#### Inject Dose

##### Attention

Use the injection technique recommended by your health care provider or nurse.

Read this whole section (Steps 9 - 12) before you start to inject.

##### Step 9

Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).

##### Figure N

##### Step 10

Push the pen straight towards the skin until you hear a click and the blue sleeve can no longer be seen (see Figure O).

##### Figure O

Click!

##### Step 11

Press the push button all the way in and hold steady for 5 seconds. Make sure the dose selector rotates back to the symbol "•". This means that you have given the full dose (see Figure P).

##### Figure P

Press...then hold 5 seconds.

##### Step 12

Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).

##### Figure Q

Panel 12

5

Throw Away Used Needle

Step 13

Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). Do not attempt to recap the needle. You could poke yourself on the back end.

Figure R

Step 14

Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).

Figure S

5

#### Throw Away Used Needle

##### Step 13

Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). Do not attempt to recap the needle. You could poke yourself on the back end.

##### Figure R

##### Step 14

Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).

##### Figure S

click!

Panel 13

6

Throw Away Used Pen

Important:

Always throw away the pen 14 days after first use according to local regulations.

Always throw away your pen and any extra needles after 14 days of use, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.

Figure T

6

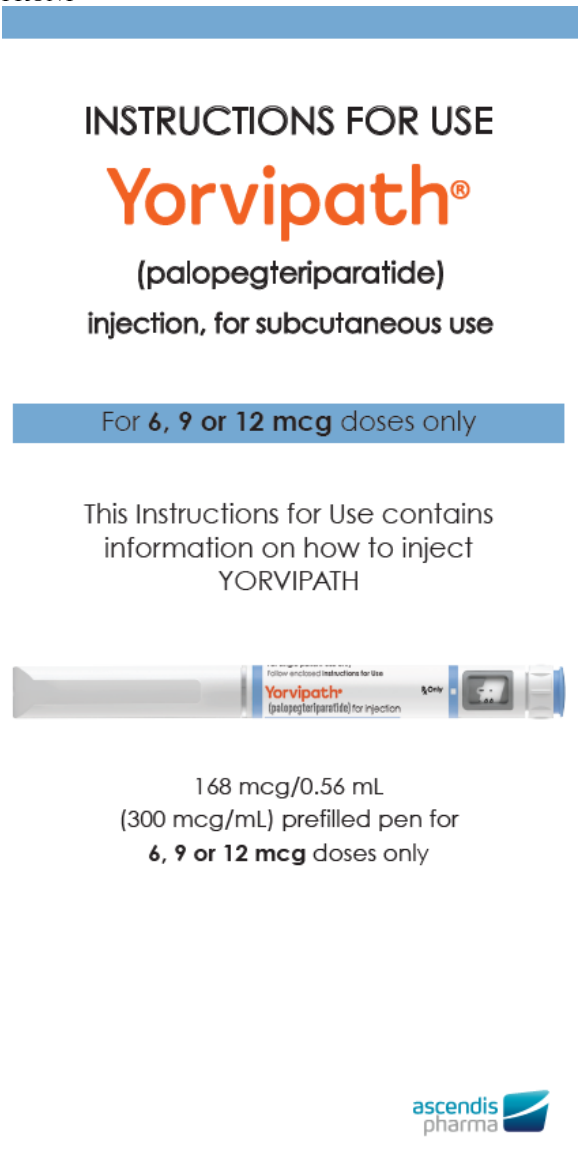

#### Throw Away Used Pen

Day 14

**Important:** Always throw away the pen 14 days after first use according to local regulations.

Always throw away your pen and any extra needles after 14 days of use, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.

##### Figure T

Label	Content
<p>FRONT</p>  <p><b>INSTRUCTIONS FOR USE</b></p> <p><b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p>For <b>6, 9 or 12 mcg</b> doses only</p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p>  <p>168 mcg/0.56 mL (300 mcg/mL) prefilled pen for <b>6, 9 or 12 mcg</b> doses only</p> <p>ascendis pharma</p>	<p><b>INSTRUCTIONS FOR USE</b> <b>Yorvipath®</b> (palopegteriparatide) injection, for subcutaneous use</p> <p>For <b>6, 9 or 12 mcg</b> doses only</p> <p>This Instructions for Use contains information on how to inject YORVIPATH</p> <p>168 mcg/0.56 mL (300 mcg/mL) prefilled pen for <b>6, 9 or 12 mcg</b> doses only</p> <p>ascendis pharma</p>
<p>Back</p>	<p><b>Additional information</b> If you need help, please ask your health care provider or nurse for advice or contact the Ascendis Pharma Helpline: <b>Ascendis Pharma Helpline:</b> Toll-free telephone number: 1-844-442-7236</p> <p>Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12 DK-2900 Hellerup Denmark</p> <p>ascendis pharma</p>

<div data-bbox="218 264 477 295" data-label="Section-Header"> <p><b>Additional information</b></p> </div> <div data-bbox="218 297 724 385" data-label="Text"> <p>If you need help, please ask your health care provider or nurse for advice or contact the Ascendis Pharma Helpline:</p> </div> <div data-bbox="218 470 526 504" data-label="Section-Header"> <p><b>Ascendis Pharma Helpline:</b></p> </div> <div data-bbox="218 501 539 560" data-label="Text"> <p>Toll-free telephone number: 1-844-442-7236</p> </div> <div data-bbox="218 631 633 745" data-label="Text"> <p>Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12 DK-2900 Hellerup Denmark</p> </div> <div data-bbox="611 1283 758 1337" data-label="Image"> </div>	<div data-bbox="758 264 774 304" data-label="Text"> <p>12661</p> </div>
<p>Panel 1</p>	<div data-bbox="858 1366 1023 1395" data-label="Section-Header"> <p><b>Troubleshooting</b></p> </div> <div data-bbox="858 1413 1217 1444" data-label="Section-Header"> <p><b>1. How often must I test the pen flow?</b></p> </div> <div data-bbox="858 1460 1388 1639" data-label="Text"> <p>You should only test the pen flow (Section 2) the first time you use a new pen (or if you think it might be damaged) to not waste medicine. The test checks to make sure the medicine flows through the pen so that you get the right doses of medicine.</p> </div> <div data-bbox="858 1657 1225 1733" data-label="Section-Header"> <p><b>2. I do not see drops appear after I have tested the pen flow 5 times. What should I do?</b></p> </div> <div data-bbox="858 1753 1185 1856" data-label="Text"> <p>If you see no drop on the needle tip after <b>5 attempts</b> it might be because there is no flow through the pen and needle.</p> </div> <div data-bbox="858 1852 1212 1980" data-label="Text"> <p>Change the needle (see Section 5, Step 13) and test the pen flow again (see Section 2, Steps A-C). You can be sure the flow works correctly when you see the drop of medicine.</p> </div> <div data-bbox="858 1973 1370 2029" data-label="Text"> <p>If it still does not work, throw away (discard) the pen and contact your health care provider.</p> </div>



## Troubleshooting

### 1. How often must I test the pen flow?

You should only test the pen flow (Section 2) the first time you use a new pen (or if you think it might be damaged) to not waste medicine. The test checks to make sure the medicine flows through the pen so that you get the right doses of medicine.

### 2. I do not see drops appear after I have tested the pen flow 5 times. What should I do?

If you see no drop on the needle tip after 5 attempts it might be because there is no flow through the pen and needle.

Change the needle (see Section 5, Step 13) and test the pen flow again (see Section 2, Steps A-C). You can be sure the flow works correctly when you see the drop of medicine.

If it still does not work, throw away (discard) the pen and contact your health care provider.

### 3. How do I know I have completed the injection?

Your injection is only completed after you have pressed the push button all the way in and the dose selector has rotated back to the "●" and you have kept the needle in the skin for 5 seconds.

### 4. Why do I have to keep holding the pen in the skin for 5 seconds?

Some medicine might flow back into the pen or flow backward from the injection site and be left on the skin. Holding the pen in the skin for 5 seconds helps to make sure that all the medicine has been injected.

### 5. I cannot dial the dose selector to the required dose. What should I do?

The pen does not allow a larger dose to be set than what is left in the pen. If your dose is larger than the amount of medicine left in the pen you will not be able to dial a full dose. You must throw away your pen and take the full dose of medicine with a new pen.

### 6. The red lock covers the needle before I start injection. What should I do?

Unscrew and throw away the needle in use (see Section 5, Step 13). Take a new needle from the box and start again from Step 1. Every box contains an extra needle.

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<p>Panel 2</p> <div> <h3>Storing Your Pen</h3> <ul style="list-style-type: none"> <li>• <b>Until first use</b>, refrigerate your pens between 2°C to 8°C (36°F to 46°F) and keep in the package to protect from light.</li> <li>• <b>After first use</b>, store your pen for 14 days at room temperature below 30°C (86°F).</li> <li>• <b>Do not</b> leave your pen in a car or another place where it can get too hot or too cold.</li> <li>• <b>Do not</b> freeze your pen.</li> <li>• Store YORVIPATH away from heat.</li> <li>• <b>Keep the YORVIPATH pen out of the reach of children.</b></li> </ul> <p>Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.</p> </div>	<h3>Storing Your Pen</h3> <ul style="list-style-type: none"> <li>• <b>Until first use</b>, refrigerate your pens between 2°C to 8°C (36°F to 46°F) and keep in the package to protect from light.</li> <li>• <b>After first use</b>, store your pen for 14 days at room temperature below 30°C (86°F).</li> <li>• <b>Do not</b> leave your pen in a car or another place where it can get too hot or too cold.</li> <li>• <b>Do not</b> freeze your pen.</li> <li>• Store YORVIPATH away from heat.</li> <li>• <b>Keep the YORVIPATH pen out of the reach of children.</b></li> </ul> <p>Tip: You should take a new pen out of the refrigerator 20 minutes before first use to allow the medicine to get to room temperature before injecting.</p>
<p>Panel 3</p>	<h3>Caring For Your Pen</h3> <ul style="list-style-type: none"> <li>• Handle your pen with care.</li> <li>• Keep your pen dry.</li> <li>• Use a moist cloth to clean your pen.</li> <li>• <b>Do not</b> drop or knock your pen against hard surfaces. If you do, test the pen flow again (Section 2, Steps A – C) before next use.</li> <li>• <b>Do not</b> apply extra force to your pen. It might be empty, damaged and no longer works properly.</li> <li>• <b>Do not</b> attempt to repair a damaged pen yourself. If your pen is damaged, contact the Ascendis Pharma Helpline.</li> </ul>

## Caring For Your Pen

- Handle your pen with care.
- Keep your pen dry.
- Use a moist cloth to clean your pen.
- **Do not** drop or knock your pen against hard surfaces. If you do, test the pen flow again (Section 2, Steps A – C) before next use.
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Panel 4

### Important Information You Need To Know Before Using Your YORVIPATH Pen

Read and follow this Instructions for Use carefully so that you inject YORVIPATH the right way.

If you do not understand or are unable to complete a step that is described in this Instructions for Use, contact your health care provider or nurse or the Ascendis Pharma Helpline.

Make sure you have received training from your health care provider or nurse before injecting. This is important to make sure that you get the correct treatment.

Inject YORVIPATH into the belly (abdomen) or in the front of the thigh.

Your pen can deliver doses of **6, 9, or 12 mcg**. It is used for injections under the skin (subcutaneous) for daily treatment of hypoparathyroidism. Your pen is a prefilled dial-a-dose throw away (disposable) pen.

It contains medicine for **14 days of use** and is intended to be used **1 time** each day. Do not use more than one injection to achieve the recommended once daily dosage. You can dial doses of **6, 9 or 12 mcg** with the pen.

#### For Correct Use

If you are blind or visually impaired or if you have lack of concentration **do not** use your pen without help. Get help from a person who is trained to use the YORVIPATH pen. Store your pen out of the reach of children and any other persons who do not know how to handle it properly.

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Store your pen out of the reach of children and any other persons who do not know how to handle it properly.

Panel 5

- Only use your pen as directed by your health care provider or nurse.
- The pen and needles are for single-patient use only. Do not share your pen or needles with other people. It might lead to infection (cross-contamination).
- Start by checking your pen to make sure it is the correct pen.
- Always check the expiration date on the pen label and needle foil before use.
- Always inspect the pen visually before use to make sure it is not damaged and medicine is clear, colorless and without particles.
- Always use a new needle for each injection.

<ul style="list-style-type: none"> <li>• Only use your pen as directed by your health care provider or nurse.</li> <li>• The pen and needles are for single-patient use only. Do not share your pen or needles with other people. It might lead to infection (cross-contamination).</li> <li>• Start by checking your pen to make sure it is the correct pen.</li> <li>• Always check the expiration date on the pen label and needle foil before use.</li> <li>• Always inspect the pen visually before use to make sure it is not damaged and medicine is clear, colorless and without particles.</li> <li>• Always use a new needle for each injection.</li> <li>• Only inject into the abdomen or front of thigh as instructed by your health care provider or nurse. Remember to change injection site for each injection and avoid skin that is red, swollen or scarred.</li> <li>• Always keep the cap on the pen when it is not in use to protect the medicine from light.</li> <li>• Remove the needle after every use. <b>Do not</b> store the pen with the needle on.</li> <li>• Always throw away your pen <b>after 14 days of use</b>, even if it still has medicine left inside. This is important to make sure that you get the right effect of your medicine.</li> <li>• By failing to follow these instructions you may not get the right dose and may therefore not get the full effect of your medicine.</li> <li>• Avoid bending or breaking off the pen needle.</li> <li>• <b>Do not</b> change the injection angle after the needle has been inserted into the skin. Changing the angle can cause the needle to bend or break off. A bent or broken needle can remain stuck in the body or remain completely under the skin. If a broken needle remains stuck in the body or remains under the skin, seek medical help right away.</li> </ul>	<ul style="list-style-type: none"> <li>• Only inject into the abdomen or front of thigh as instructed by your health care provider or nurse. Remember to change injection site for each injection and avoid skin that is red, swollen or scarred.</li> <li>• Always keep the cap on the pen when it is not in use to protect the medicine from light.</li> <li>• Remove the needle after every use. <b>Do not</b> store the pen with the needle on.</li> <li>• Always throw away your pen <b>after 14 days of use</b>, even if it still has medicine left inside. This is important to make sure that you get the right effect of your medicine.</li> <li>• By failing to follow these instructions you may not get the right dose and may therefore not get the full effect of your medicine.</li> <li>• Avoid bending or breaking off the pen needle.</li> <li>• <b>Do not</b> change the injection angle after the needle has been inserted into the skin. Changing the angle can cause the needle to bend or break off. A bent or broken needle can remain stuck in the body or remain completely under the skin. If a broken needle remains stuck in the body or remains under the skin, seek medical help right away.</li> </ul>
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Panel 6

## Compatible Pen Needles

In each of the **two** inner boxes there are **15** disposable Clickfine® AutoProtect™ Needles (31G x 5mm) together with a YORVIPATH prefilled pen for doses of 6, 9 or 12 mcg. Always use the needles that come with YORVIPATH pen for your injections.

## For Correct Disposal

Always put your used YORVIPATH needles in an FDA-cleared sharps disposal container **right away after use**.

Always put your used pen in an FDA-cleared sharps disposal container **after 14 days of use**.

Do not throw away (dispose of) YORVIPATH in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic.
- can be closed with a tight-fitting, puncture resistant lid, without sharps being able to come out.
- upright and stable during use.
- leak-resistant.
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>. Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

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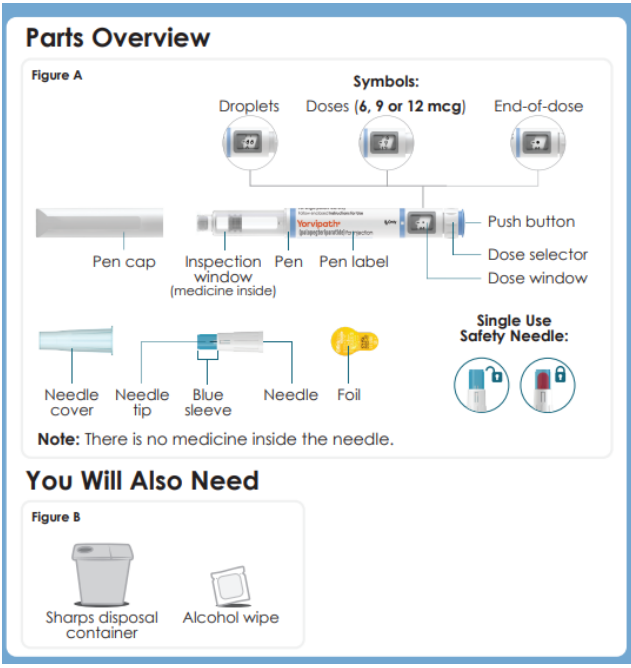
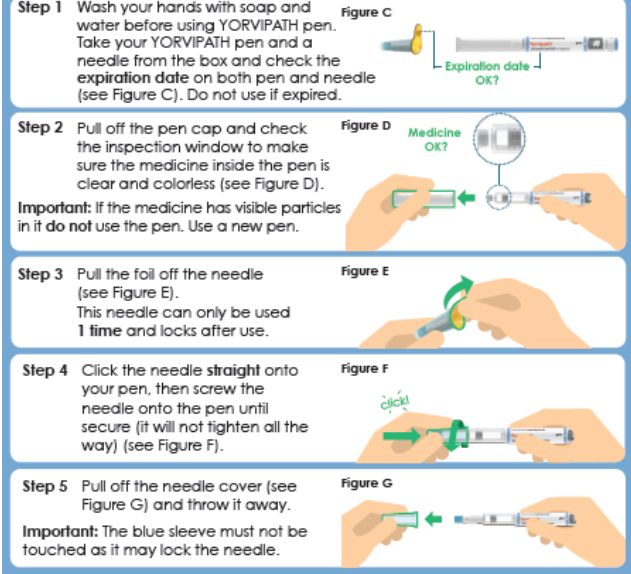
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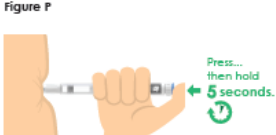





- made of heavy-duty plastic.
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When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>. Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Label	Content
<p>Panel 7</p>  <p><b>Parts Overview</b></p> <p>Figure A</p> <p>Symbols:</p> <ul style="list-style-type: none"> <li>Droplets</li> <li>Doses (6, 9 or 12 mcg)</li> <li>End-of-dose</li> </ul> <p>Pen cap, Inspection window (medicine inside), Pen, Pen label, Push button, Dose selector, Dose window</p> <p>Single Use Safety Needle:</p> <ul style="list-style-type: none"> <li>Needle cover</li> <li>Needle tip</li> <li>Blue sleeve</li> <li>Needle</li> <li>Foil</li> </ul> <p>Note: There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p>Figure B</p> <ul style="list-style-type: none"> <li>Sharps disposal container</li> <li>Alcohol wipe</li> </ul>	<p><b>Parts Overview</b></p> <p><b>Figure A</b> <b>Symbols:</b></p> <ul style="list-style-type: none"> <li>-Droplets</li> <li>-Doses (6, 9 or 12 mcg)</li> <li>-End-of-dose</li> <li>-Pen cap</li> <li>-Inspection window (medicine inside)</li> <li>-Pen</li> <li>-Pen label</li> <li>-Push button</li> <li>-Dose selector</li> <li>-Dose window</li> <li>-Needle cover</li> <li>-Needle tip</li> <li>-Blue sleeve</li> <li>-Needle</li> <li>-Foil</li> </ul> <p><b>Single Use Safety Needle:</b></p> <p><b>Note:</b> There is no medicine inside the needle.</p> <p><b>You Will Also Need</b></p> <p><b>Figure B</b></p> <ul style="list-style-type: none"> <li>Sharps disposal container</li> <li>Alcohol wipe</li> </ul>
<p>Panel 8</p> <p><b>1 Prepare Pen And Needle</b></p> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the expiration date on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it do not use the pen. Use a new pen.</p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used <b>1 time</b> and locks after use.</p> <p><b>Step 4</b> Click the needle <b>straight</b> onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p> 	<p><b>1 Prepare Pen And Needle</b></p> <p><b>Step 1</b> Wash your hands with soap and water before using YORVIPATH pen. Take your YORVIPATH pen and a needle from the box and check the <b>expiration date</b> on both pen and needle (see Figure C). Do not use if expired.</p> <p><b>Figure C</b> Expiration date OK?</p> <p><b>Step 2</b> Pull off the pen cap and check the inspection window to make sure the medicine inside the pen is clear and colorless (see Figure D). <b>Important:</b> If the medicine has visible particles in it <b>do not</b> use the pen. Use a new pen.</p> <p><b>Figure D</b> Medicine OK?</p> <p><b>Step 3</b> Pull the foil off the needle (see Figure E). This needle can only be used <b>1 time</b> and locks after use.</p> <p><b>Figure E</b></p> <p><b>Step 4</b> Click the needle <b>straight</b> onto your pen, then screw the needle onto the pen until secure (it will not tighten all the way) (see Figure F).</p> <p><b>Figure F</b> Click!</p> <p><b>Step 5</b> Pull off the needle cover (see Figure G) and throw it away. <b>Important:</b> The blue sleeve must not be touched as it may lock the needle.</p>



<p>Panel 9</p> <div data-bbox="204 255 831 909"> <h2>2 If New Pen, Test Pen Flow</h2> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H).</p> <p><b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Figure H</b></p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up.</p> <p><b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Figure I</b></p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the dose selector rotates back to the symbol "••" (see Figure J).</p> <p><b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> <p><b>Figure J</b></p> </div>	<p><b>Figure G</b></p> <p>2</p> <p><b>If New Pen, Test Pen Flow</b></p> <p>Day 1</p> <p><b>Attention</b> Only test pen flow (Steps A – C) the first time you use a new pen. If your pen is already in use, go to section "3 Prepare Injection".</p> <p><b>Step A</b> Turn the dose selector clockwise (to the right) 2 clicks until you see the droplet symbol "••" in the dose window (see Figure H). <b>Note:</b> You can always correct the selection by turning the dose selector.</p> <p><b>Figure H</b></p> <p><b>Step B</b> Make any air bubbles rise to the top of the pen by tapping the inspection window (see Figure I). Keep the pen with the needle tip pointed up. <b>Note:</b> Tiny air bubbles are ok.</p> <p><b>Figure I</b> tap tap</p> <p><b>Step C</b> Press the push button and watch drops of medicine come out of the needle tip. When you press, make sure that the dose selector rotates back to the symbol "••" (see Figure J). <b>Important:</b> If you do not see drops of medicine, repeat this test (Steps A – C) up to 5 times. If drops are still not seen, change the needle and repeat the test.</p> <p><b>Figure J</b></p>
<p>Panel 10</p> <div data-bbox="204 1171 831 1825"> <h2>3 Prepare Injection and Select Dose</h2> <p><b>Step 6</b> Choose injection site. There are <b>two</b> regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b></p> <p><b>Stomach (Abdomen)</b> at least 2 inches away from the belly button</p> <p><b>Thighs</b></p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b></p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (6, 9 or 12 mcg) by turning the dose selector clockwise (to the right) (see Figure M).</p> <p><b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> <p><b>Figure M</b></p> </div>	<p>3</p> <p><b>Prepare Injection and Select Dose</b></p> <p><b>Step 6</b> Choose injection site. There are <b>two</b> regions of your body you can inject into (see Figure K). Avoid injecting where skin is red, swollen or scarred. Choose a different injection site each time you inject.</p> <p><b>Figure K</b> Front <b>Stomach (Abdomen)</b> at least 2 inches away from the belly button <b>Thighs</b></p> <p><b>Step 7</b> Wash your hands and clean the injection site with an alcohol wipe (see Figure L).</p> <p><b>Figure L</b> Use alcohol wipe</p> <p><b>Step 8</b> Select your dose as prescribed by your health care provider (6, 9 or 12 mcg) by turning the dose selector clockwise (to the right) (see Figure M). <b>Important:</b> Make sure not to press the push button while selecting your dose to not spill medicine. <b>Note:</b> Always throw away your pen and use another pen if you cannot dial a full dose.</p> <p><b>Figure M</b></p>
<p>Panel 11</p>	<p>4</p> <p><b>Inject Dose</b></p> <p><b>Attention</b></p>

<div><div>4</div><div>Inject Dose</div></div> <div><div>Attention</div><div>Use the injection technique recommended by your health care provider or nurse. Read this whole section (Steps 9 - 12) before you start to inject.</div></div> <div><div>Step 9</div><div>Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).</div><div>Figure N</div><div></div></div> <div><div>Step 10</div><div>Push the pen straight towards the skin until you hear a click and the blue sleeve can no longer be seen (see Figure O).</div><div>Figure O</div><div></div></div> <div><div>Step 11</div><div>Press the push button all the way in and hold steady for 5 seconds. Make sure the dose selector rotates back to the symbol "•". This means that you have given the full dose (see Figure P).</div><div>Figure P</div><div></div></div> <div><div>Step 12</div><div>Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).</div><div>Figure Q</div><div></div></div>	<p>Use the injection technique recommended by your health care provider or nurse. Read this whole section (Steps 9 - 12) before you start to inject.</p> <p><b>Step 9</b> Hold the pen so that the blue sleeve is placed on the injection site. Make sure you can see the dose window (see Figure N).</p> <p><b>Figure N</b></p> <p><b>Step 10</b> <b>Push the pen straight towards the skin</b> until you hear a click and the blue sleeve can no longer be seen (see Figure O).</p> <p><b>Figure O</b> Click!</p> <p><b>Step 11</b> Press the push button all the way in and hold steady for <b>5 seconds</b>. Make sure the dose selector rotates back to the symbol "•". This means that you have given the full dose (see Figure P).</p> <p><b>Figure P</b> Press...then hold <b>5 seconds</b>.</p> <p><b>Step 12</b> Slowly remove the pen from the injection site. The blue sleeve automatically locks around the needle and a red lock is seen (see Figure Q).</p> <p><b>Figure Q</b></p>
<div>Panel 12</div> <div><div>5</div><div>Throw Away Used Needle</div></div> <div><div>Step 13</div><div>Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). Do not attempt to recap the needle. You could poke yourself on the back end.</div><div>Figure R</div><div></div></div> <div><div>Step 14</div><div>Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).</div><div>Figure S</div><div></div></div>	<p>5</p> <p><b>Throw Away Used Needle</b></p> <p><b>Step 13</b> Unscrew the needle and throw away the needle safely in accordance with local regulations (see Figure R). <b>Do not</b> attempt to recap the needle. You could poke yourself on the back end.</p> <p><b>Figure R</b></p> <p><b>Step 14</b> Click the pen cap firmly onto the pen to protect it between injections and to protect the medicine from light (see Figure S).</p> <p><b>Figure S</b> click!</p>
<div>Panel 13</div> <div><div>6</div><div>Throw Away Used Pen</div><div></div></div> <div><div>Important:</div><div>Always throw away the pen 14 days after first use according to local regulations.</div><div>Figure T</div><div></div></div> <div><div>Always throw away your pen and any extra needles after 14 days of use, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.</div></div>	<p>6</p> <p><b>Throw Away Used Pen</b> Day 14</p> <p><b>Important:</b> Always throw away the pen <b>14 days after first use</b> according to local regulations.</p> <p>Always throw away your pen and any extra needles after <b>14 days of use</b>, even if it still has medicine inside (see Figure T). This is important to make sure that you get the full effect of your medicine.</p> <p><b>Figure T</b></p>