

**Label**



**yuviwel**<sup>®</sup> (YOU-vih-well)  
(navepegritide) for injection, for subcutaneous use

**For Use Under the Skin Only (subcutaneous)**  
**Single-Dose Vial**  
**Discard unused Portion**

1 time a week injection

This leaflet contains:  
PRESCRIBING INFORMATION and  
INSTRUCTIONS FOR USE



**Additional information**

If you need help, please ask your healthcare provider for advice. You may also call the Ascendis Pharma Customer Support toll-free number at 1-844-442-7236 (1-844-44ASCENDIS) for assistance or additional training, if needed.



**Scan To Watch the Optional  
Instructional Video**



Yuviwel.com

WLSLB-10281418

**Content**

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Ascendis Pharma

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Yuviwel.com

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### INSTRUCTIONS FOR USE

**yuviwel**<sup>®</sup> (YOU-vih-well)  
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For Use Under the Skin Only (subcutaneous)

This Instructions for Use contains information on how to prepare and inject Yuviwel.

VA-SUB-102804 V1

## Content

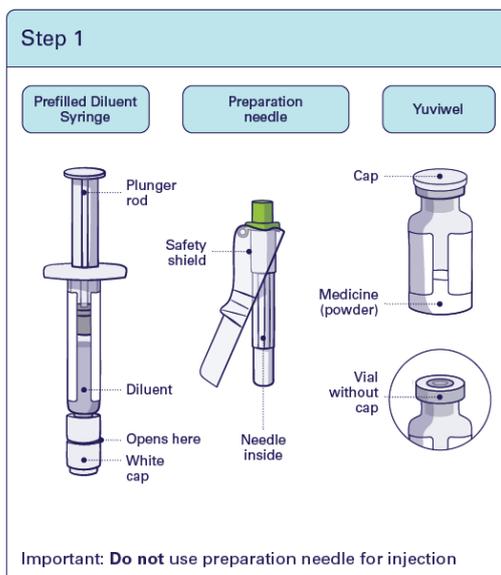
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## Parts Overview



## Parts Overview

### Step 1

Symbols:

Prefilled Diluent Syringe

Plunger rod

Diluent

Opens here

White cap

Preparation needle

Safety shield

Needle inside

Yuviwel

Cap

Medicine (powder)

Vial without cap

Important: **Do not** use preparation needle for injection

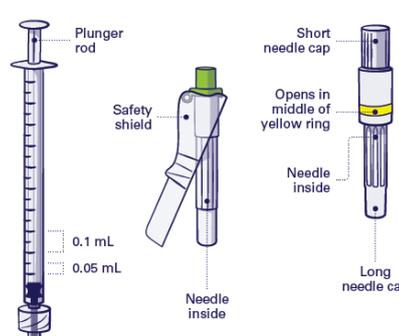
## Label

Step 2 and Step 3

Injection syringe

Preparation needle

Injection needle



Important: **Do not** use preparation needle for injection

**Supplies Not Included:**  
You will also need a sharps disposal container and alcohol wipes.

### Get to know Yuviwel

Make sure you have received training from your healthcare provider before injecting.

Read and follow the Instructions for Use step-by-step to make sure you inject Yuviwel the right way.

**Important:** Prior to use, read the Instructions for Use carefully even if you have used a similar product. The steps may not be the same.

If you are blind or visually impaired, do not use Yuviwel without help from a person who is trained to use it.

#### How Yuviwel is supplied and injected

Yuviwel is injected under the skin (subcutaneous injection) 1 time a week.

Each Yuviwel carton includes 4 Kits, with 1 Prescribing Information and 1 Instructions for Use.

Yuviwel is available in the following strengths:

**1.3 mg/vial      2.8 mg/vial      5.5 mg/vial**

**Always check that you inject the dose strength prescribed by your healthcare provider.**

If you are injecting yourself with Yuviwel, you should use the stomach area (2 inches from belly button) or thighs as injection sites.

If someone else gives you the Yuviwel injection, the buttocks or the back of the upper arms can be used as injection sites.

Only inject into injection sites instructed by your healthcare provider.

## Content

### Step 2 and Step 3

Symbols:

Injection syringe

Plunger rod

0.1 mL

0.05 mL

Preparation needle

Safety shield

Needle inside

Injection needle

Short needle cap

Opens in middle of yellow ring

Needle inside

Long needle cap

Important: **Do not** use preparation needle for injection

### Supplies Not Included:

You will also need a sharps disposal container and alcohol wipes.

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### Important before starting Yuviwel

Check all parts and their packaging for signs of damage.

**Do not use** if any parts or packaging appear damaged. Use a new Kit.

Your healthcare provider may prescribe a dose that is more than 1 milliliter (mL) and requires the use of two Kits to deliver two injections for a complete dose.

If you have been prescribed a dose that is more than 1 mL:

- Prepare and give your first injection, using one Kit (follow Steps 1 through 3.10)
- Then, using a new Kit, immediately prepare and give a second injection by repeating steps 1 through 3.10.

Check the expiration date on the Kit. **Do not use** Yuviwel if expired. Use a new Kit.

**Only use** the vial, needles, and syringes that come in your Kit.

If you do not have an alcohol wipe, use soap and water to clean the injection site and the grey rubber at the top of the vial.

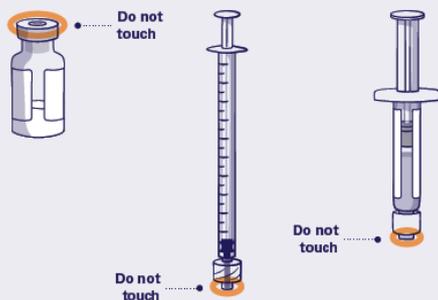
The vial, needles, and syringes in the Kit are for **one time use only**.

**Do not reuse** any of the parts. **Do not recap** needles.

**Be careful** when handling needles to reduce the risk of needlestick injury and infection.

**Do not throw away** opened or used needles in your household trash. Use a sharps disposal container.

After unpacking and to **avoid** contamination, **do not touch** the top of the vial, the tip of the Prefilled Diluent Syringe or the tip of the injection syringe.



**Do not 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 under the skin. If a needle breaks in your skin, get medical help right away.

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### Throwing away Yuviwel parts

Throw away (dispose of) used needles, syringes and the vial in an FDA-cleared sharps disposal container right away after use.

- Do not throw away (dispose of) used needles and syringes in the household trash.
- Do not reuse needles. Always use a new needle for each injection.

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, and
- 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. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal)

### Storing Yuviwel

**Store Yuviwel refrigerated between 36°F to 46°F (2°C to 8°C)** in the original carton to protect from light. Do not freeze. Yuviwel can also be stored at room temperature up to 86°F (30°C) for up to 6 months and can be returned to the refrigerator within the 6 months.

Do not use Yuviwel past the expiration date or 6 months after the date it was first removed from the refrigerator (whichever comes first).

Keep Yuviwel and all medicines out of the reach of children. Small parts in the Kit may cause a choking hazard for children and pets.

Yuviwel does not contain preservatives. **After mixing**, Yuviwel can be stored at room temperature up to 86°F (30°C) and must be used within **4 hours**. Throw away unused medicine. Throw away medicine if not used within 4 hours after mixing.

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### Step 1

## Prepare medicine

#### Gather supplies:

1 Kit, 2 alcohol wipes and a sharps disposal container.

**Note: If the Kit has been stored in the refrigerator,** let the vial and Prefilled Diluent Syringe sit at room temperature for about 30 minutes before mixing (reconstitution).



Scan QR code to watch optional instruction video



**A**



**1.1** Wash hands with soap and water or use hand sanitizer.

**1.2** Flip off the cap of the vial (See A). You can use 1 or 2 hands to remove the cap.

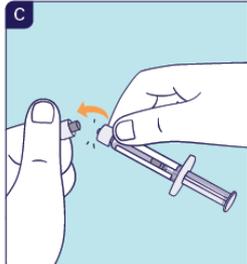
**B**



**1.3** Wipe the grey rubber at the top of the vial with an alcohol wipe (See B).

**Do not** touch the top after cleaning it.

**C**

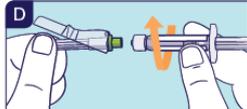


**1.4** Break off the white cap of the Prefilled Diluent Syringe (See C).

**Do not** touch the tip of the Prefilled Diluent Syringe after breaking off the cap.

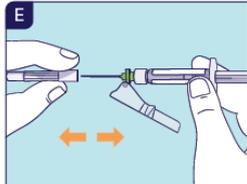
**Be careful** not to push the plunger rod to avoid spilling diluent. If you spill diluent, use a new Kit.

**D**



**1.5** Unpack preparation needle and screw it on the Prefilled Diluent Syringe (See D).

**E**



**1.6** Pull back the safety shield and remove the needle cap (See E).

Throw away (dispose of) the needle cap.

If the safety shield locks, use a new Kit.

## Content

### Step 1

## Prepare medicine

#### Gather supplies:

1 Kit,  
2 alcohol wipes and a sharps disposal container.

**Note: If the Kit has been stored in the refrigerator,** let the vial and Prefilled Diluent Syringe sit at room temperature for about 30 minutes before mixing (reconstitution).

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#### B

**1.3** Wipe the grey rubber at the top of the vial with an alcohol wipe (See B).

**Do not** touch the top after cleaning it.

#### C

**1.4** Break off the white cap of the Prefilled Diluent Syringe (See C).

**Do not** touch the tip of the Prefilled Diluent Syringe after breaking off the cap.

**Be careful** not to push the plunger rod to avoid spilling diluent. If you spill diluent, use a new Kit.

#### D

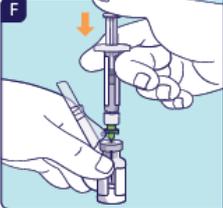
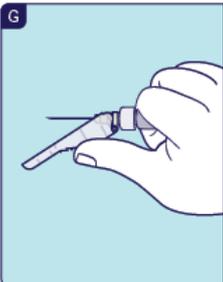
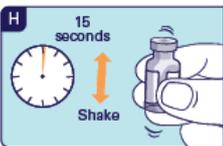
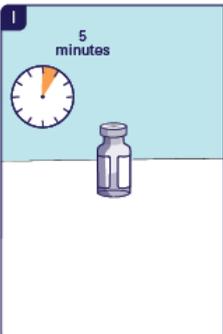
**1.5** Unpack preparation needle and screw it on the Prefilled Diluent Syringe (See D).

#### E

**1.6** Pull back the safety shield and remove the needle cap (See E).

Throw away (dispose of) the needle cap.

If the safety shield locks, use a new Kit.

	<p><b>F</b></p> <p><b>1.7</b> Insert preparation needle into the center of the circle on top of the vial (See F).</p> <p><b>1.8</b> Push all the diluent into the vial (See F).</p> <p><b>1.9</b> Pull preparation needle out of the vial.</p>
	<p><b>G</b></p> <p><b>1.10</b> To avoid a needle stick injury, push the safety shield over preparation needle with 1 hand or press the shield against a hard surface directly after use until you hear it click and it locks (See G).</p> <p><b>1.11</b> Place the Prefilled Diluent Syringe and preparation needle in the sharps disposal container.</p>
	<p><b>H</b></p> <p><b>1.12</b> Hold the glass part of the vial and shake up and down for 15 seconds (See H). <b>Do not</b> swirl or roll as the medicine will not be fully mixed.</p>
	<p><b>I</b></p> <p><b>1.13</b> Put the vial down and leave it for 5 minutes to let the medicine settle (See I).</p> <p><b>1.14</b> Check the medicine. The medicine should be clear and colorless. You may see air bubbles. This is normal.</p> <p><b>Do not</b> use the medicine if you see particles.</p> <p>Throw away medicine if not used within 4 hours after mixing.</p>

**F**

**1.7** Insert preparation needle into the center of the circle on top of the vial (See F).

**1.8** Push all the diluent into the vial (See F).

**1.9** Pull preparation needle out of the vial.

**G**

**1.10** To avoid a needle stick injury, push the safety shield over preparation needle with 1 hand or press the shield against a hard surface directly after use until you hear it click and it locks (See G).

**1.11** Place the Prefilled Diluent Syringe and preparation needle in the sharps disposal container.

**H**

15 seconds  
Shake

**1.12** Hold the glass part of the vial and shake up and down for 15 seconds (See H). **Do not** swirl or roll as the medicine will not be fully mixed.

**I**

5 minutes

**1.13** Put the vial down and leave it for 5 minutes to let the medicine settle (See I).

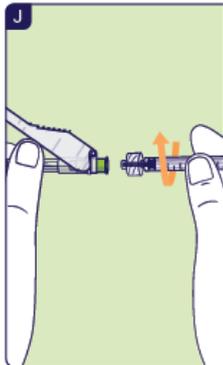
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**Step 2**  
**Prepare injection**

**J**



**2.1** Unpack the injection syringe and a new preparation needle.

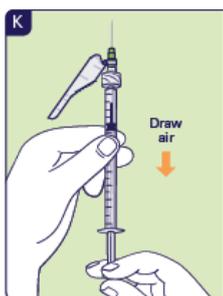
**2.2** Screw a new preparation needle on the injection syringe (See J).

**2.3** Pull back the safety shield and remove the needle cap.

**Do not** remove needle cap until ready to continue.

If the safety shield locks unexpectedly, use a new Kit.

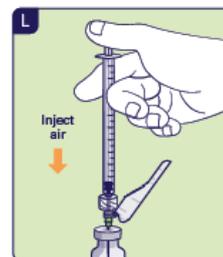
**K**



**2.4** Pull the plunger rod out to draw air into the injection syringe equal to the prescribed Yuviwel dose in milliliters (mL) (See K).

This is needed to withdraw the right dose.

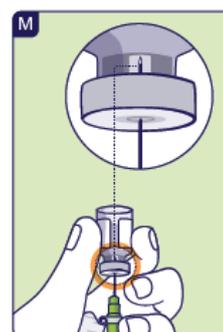
**L**



**2.5** Insert preparation needle into the center of the circle on top of the vial and inject the air (See L).

**2.6** Turn the vial and the injection syringe upside down.

**M**



**2.7** Position preparation needle within the liquid to allow the medicine to be withdrawn.

If you insert the needle all the way in, you will only draw air and no medicine (See M).

Turn the vial to the gap in the vial label to see the medicine better.

**Step 2**  
**Prepare injection**

**J**  
**2.1** Unpack the injection syringe and a new preparation needle.

**2.2** Screw a new preparation needle on the injection syringe (See J).

**2.3** Pull back the safety shield and remove the needle cap.

**Do not** remove needle cap until ready to continue.

If the safety shield locks unexpectedly, use a new Kit.

**K**  
Draw air

**2.4** Pull the plunger rod out to draw air into the injection syringe equal to the prescribed Yuviwel dose in milliliters (mL) (See K).

This is needed to withdraw the right dose.

**L**  
Inject air

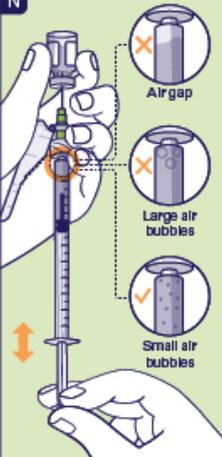
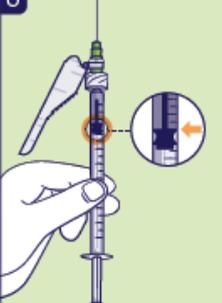
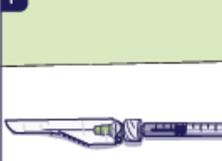
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If you insert the needle all the way in, you will only draw air and no medicine (See M).

Turn the vial to the gap in the vial label to see the medicine better.

<p><b>N</b></p> 	<p><b>2.8</b> Withdraw the <b>prescribed dose</b>, by pulling and pushing the plunger to remove air gaps and large air bubbles (See N).</p> <p>Tapping the injection syringe may help air rise to the top.</p> <p><b>Before you continue:</b> Check for air gaps at the top of the syringe.</p> <p>Check for large air bubbles.</p> <p>If you see any air gaps or large air bubbles, pull and push the plunger to remove. Small air bubbles are okay (See N).</p>
<p><b>O</b></p> 	<p><b>2.9</b> Check that you have the right dose (See O).</p> <p>The plunger has 2 rings. Your dose should be in line with the top ring of the black part of the plunger.</p> <p>If you did not withdraw the right dose, go back to step 2.7.</p> <p><b>2.10</b> Pull preparation needle out of the vial.</p>
<p><b>P</b></p> 	<p><b>2.11</b> Lock the safety shield over the preparation needle (See G).</p> <p><b>2.12</b> Rest the injection syringe carefully on the table while you unpack the injection needle (See P).</p>

**N**

Air gap  
Large air bubbles  
Small air bubbles

**2.8** Withdraw the **prescribed dose**, by pulling and pushing the plunger to remove air gaps and large air bubbles (See N).

Tapping the injection syringe may help air rise to the top.

**Before you continue:**

Check for air gaps at the top of the syringe.

Check for large air bubbles.

If you see any air gaps or large air bubbles, pull and push the plunger to remove. Small air bubbles are okay (See N).

**O**

**2.9** Check that you have the right dose (See O).

The plunger has 2 rings. Your dose should be in line with the top ring of the black part of the plunger.

If you did not withdraw the right dose, go back to step 2.7.

**2.10** Pull preparation needle out of the vial.

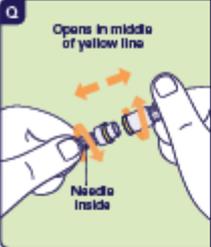
**P**

**2.11** Lock the safety shield over the preparation needle (See G).

**2.12** Rest the injection syringe carefully on the table while you unpack the injection needle (See P).

**Step 3**  
**Inject and throw away**

**Q**



Opens in middle of yellow line

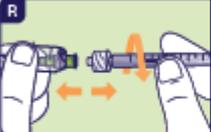
Needle inside

**3.1** Gather the injection needle from the Kit.

**3.2** Twist and pull off the short needle cap of the injection needle (See Q).

Twisting both ways on the needle may help. You may have to twist hard.

**R**



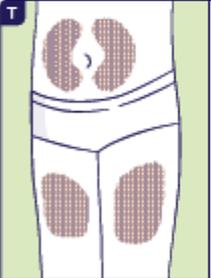
**3.3** Unscrew the used preparation needle and place in the sharps disposal container (See R).

**S**



**3.4** Screw the injection needle onto the injection syringe (See S).

**T**

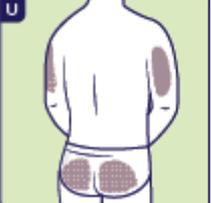


**3.5** Choose a site for injection. You can inject in either the stomach area (2 inches from the belly button) or thighs (See T).

Choose a different injection site each time.

If someone else gives you the Yuviwel injection, the buttocks or the back of the upper arms can be used as injection sites (See T and U).

**U**



Avoid injecting where skin is red, swollen, or scarred.

**V**



**3.6** Clean the injection site with an alcohol wipe (See V).

**Step 3**  
**Inject and throw away**

**Q**  
Opens in middle of yellow line  
Needle inside

**3.1** Gather the injection needle from the Kit.

**3.2** Twist and pull off the short needle cap of the injection needle (See Q).

Twisting both ways on the needle may help. You may have to twist hard.

**R**  
**3.3** Unscrew the used preparation needle and place in the sharps disposal container (See R).

**S**  
**3.4** Screw the injection needle onto the injection syringe (See S).

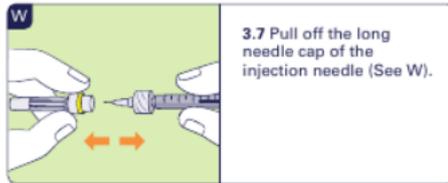
**T and U**  
**3.5** Choose a site for injection. You can inject in either the stomach area (2 inches from the belly button) or thighs (See T).

**Choose a different injection site each time.**

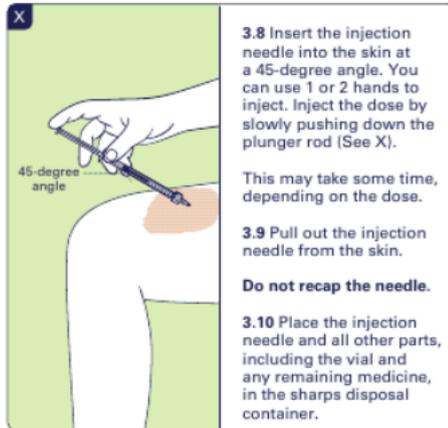
If someone else gives you the Yuviwel injection, the buttocks or the back of the upper arms can be used as injection sites (See T and U).

**Avoid injecting** where skin is red, swollen, or scarred.

**3.6** Clean the injection site with an alcohol wipe (See V).



**3.7** Pull off the long needle cap of the injection needle (See W).



**3.8** Insert the injection needle into the skin at a 45-degree angle. You can use 1 or 2 hands to inject. Inject the dose by slowly pushing down the plunger rod (See X).

This may take some time, depending on the dose.

**3.9** Pull out the injection needle from the skin.

**Do not recap the needle.**

**3.10** Place the injection needle and all other parts, including the vial and any remaining medicine, in the sharps disposal container.

**Important**

If your Yuviwel dose is more than 1 mL each week:

If your prescribed dose is more than 1 mL, get a new Kit and repeat steps 1 through 3.10 to give a second injection for a complete dose. The second injection must be given right after the first injection, **using a different injection site.**

**Remember to choose a different injection site for each Yuviwel injection.**

**Do not reuse any parts for the 2 injections.**

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**W**

**3.7** Pull off the long needle cap of the injection needle (See W).

**X**

45-degree angle

**3.8** Insert the injection needle into the skin at a 45-degree angle. You can use 1 or 2 hands to inject. Inject the dose by slowly pushing down the plunger rod (See X).

This may take some time, depending on the dose.

**3.9** Pull out the injection needle from the skin.

**Do not recap the needle.**

**3.10** Place the injection needle and all other parts, including the vial and any remaining medicine, in the sharps disposal container.

**Important**

If your Yuviwel dose is more than 1 mL each week:

If your prescribed dose is more than 1 mL, get a new Kit and repeat steps 1 through 3.10 to give a second injection for a complete dose. The second injection must be given right after the first injection, **using a different injection site.**

**Remember to choose a different injection site for each Yuviwel injection.**

**Do not reuse any parts for the 2 injections.**

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