



# Instructions for Use

## HYMPAVZI™ prefilled pen

(him-PAV-zee)  
Injection, for subcutaneous use  
single-dose prefilled pen

150 mg/mL

This Instructions for Use contains information on how to inject HYMPAVZI.

Read this Instructions for Use carefully before using HYMPAVZI prefilled pen and each time you get a refill prescription as there may be new information.

Your healthcare provider should show you or your caregiver how to prepare and inject a dose of HYMPAVZI the right way before you use it for the first time. **Do not inject yourself or someone else until you have been shown how to inject HYMPAVZI.**

Please see full [Prescribing Information](#), including [Patient Information](#) and [Instructions for Use](#), at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

### Important Information You Need to Know Before Injecting HYMPAVZI

- Each HYMPAVZI prefilled pen is a single-dose prefilled pen (called “pen” in this Instructions for Use). The HYMPAVZI prefilled pen contains 150 mg of HYMPAVZI for injection under the skin (subcutaneously).
- **Do not** inject HYMPAVZI into a vein.
- To help you remember when to inject HYMPAVZI, you can mark your calendar ahead of time. Call your healthcare provider if you or your caregiver have any questions about the right way to inject HYMPAVZI, or call the helpline at 1-888-496-7289 (1-888 HYMPAV-Z).
- Use HYMPAVZI exactly as prescribed by your healthcare provider.
- HYMPAVZI is not made with natural rubber latex.

### Storing HYMPAVZI

- Store HYMPAVZI in a refrigerator at 36°F to 46°F (2°C to 8°C).
- Store HYMPAVZI in the original carton to protect from light.
- If needed, HYMPAVZI may be stored one time at room temperature, up to 86°F (30°C) in the original carton for up to 7 days. **Do not** return HYMPAVZI to the refrigerator after storing at room temperature.
- Throw away (dispose of) HYMPAVZI that has been left out of the refrigerator for more than 7 days.
- **Do not** freeze HYMPAVZI.
- **Do not** shake HYMPAVZI.
- **Do not** use past the expiration date (EXP) printed on the HYMPAVZI prefilled pen.
- **Keep HYMPAVZI and all medicines out of the reach of children.**

Please see full [Important Safety Information](#) at the end and full [Prescribing Information](#), including [Patient Information](#) and [Instructions for Use](#), at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

## Supplies Needed For HYMPAVZI Injection

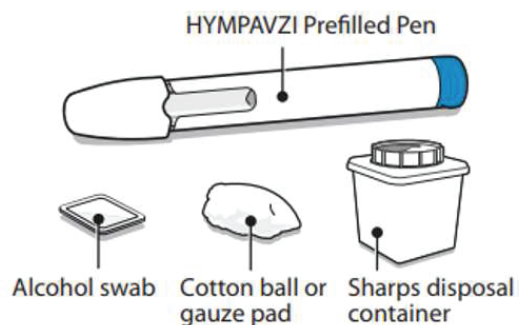
Gather the following supplies on a clean flat surface:

**Included in the carton:**

- 1 HYMPAVZI prefilled pen

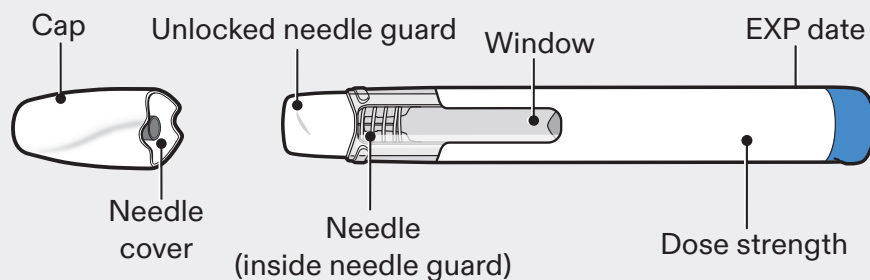
**Not included in the carton:**

- 1 alcohol swab
- 1 cotton ball or gauze pad
- 1 FDA-cleared sharps disposal container for pen disposal  
(see “**Step 10 – Disposal of Pen**” and “**Safe Pen Disposal**” information section)

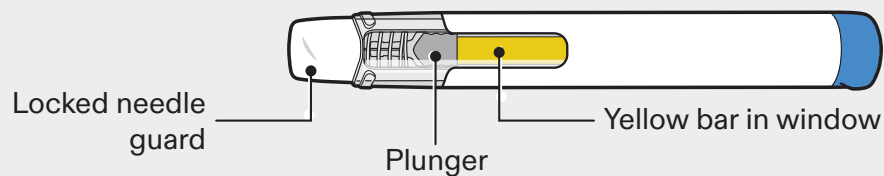


### HYMPAVZI prefilled pen

#### HYMPAVZI prefilled pen *BEFORE* use:



#### HYMPAVZI prefilled pen *AFTER* use:



Please see full Important Safety Information at the end and full [Prescribing Information](#), including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

# Preparing to Inject HYMPAVZI

Step  
1

## Getting Ready

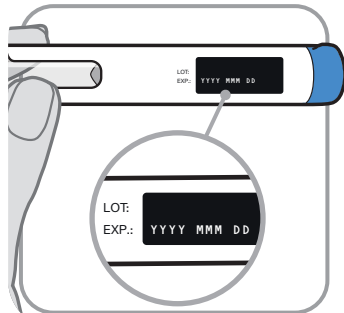
- **Remove** the pen from its carton and keep out of direct sunlight.
- **Make sure** the name HYMPAVZI appears on the carton and pen label.
- **Check the pen** for any visible damage such as cracks or leaks.
- **Wash and dry** your hands.
- **Do not remove the cap until you are ready to inject.**
- **Throw away (dispose of)** the pen if it is damaged, or if the pen or the carton containing the pen has been dropped.
- **Do not** use the pen if:
  - it has been stored in direct light. Exposure to room light during dose preparation and injection is acceptable.
  - it has been frozen or thawed or it has been out of the refrigerator for more than 7 days.

**Note:** For a more comfortable injection, allow the pen to warm up to room temperature in the carton away from direct sunlight for about 15 to 30 minutes.

**Do not** use any other methods to warm up the pen, such as warming the pen in a microwave or hot water.

Step  
2

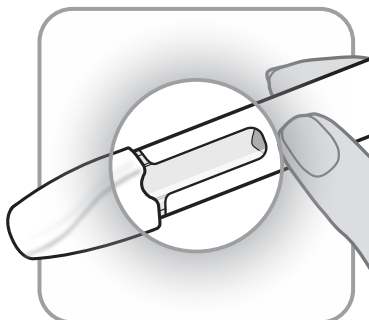
## Check Expiration Date



- **Check** the expiration date (EXP) printed on the pen label.
- **Do not** use if the expiration date (EXP) has passed.

Step  
3

## Check Medicine



- **Look** carefully at the medicine through the window on the pen.
  - The medicine should be clear and colorless to light yellow.
  - **Do not** use the pen if the medicine is cloudy, dark yellow, or contains flakes or particles.

**Note:** It is normal to see air bubbles in the window.

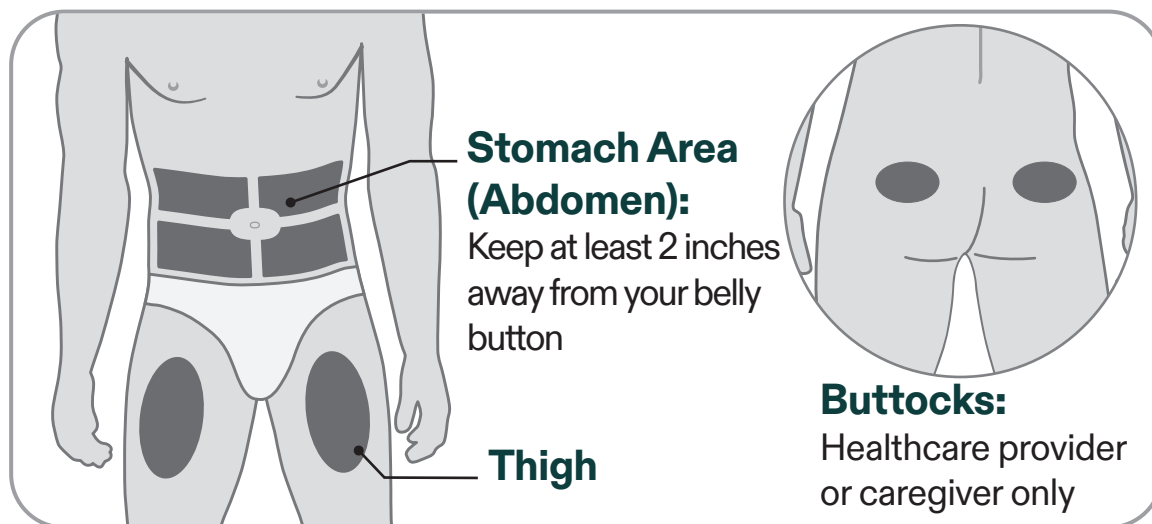
**If you have any questions about the medicine, contact your healthcare provider.**

Please see full Important Safety Information at the end and full [Prescribing Information](#), including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

## Preparing to Inject HYMPAVZI (cont'd)

Step  
4

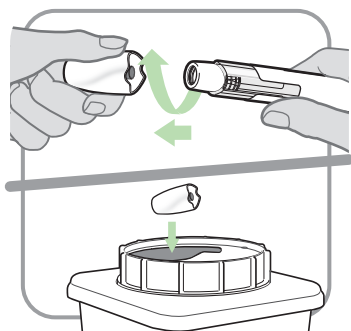
### Choose and Clean Your Injection Site



- **Choose** an injection site on your stomach area (abdomen) or thigh unless a different site has been suggested by your healthcare provider. HYMPAVZI may also be injected into your buttocks by a healthcare provider or caregiver only. Keep at least 2 inches away from your belly button.
- **Change (rotate)** the injection site each time you give yourself an injection of HYMPAVZI and away from any other medicine given under your skin. You may use the same area of your body but be sure to choose a different injection site in that area.
- **Clean** the injection site with soap and water, or an alcohol swab.
- **Allow** the site to air dry. **Do not** touch, fan, or blow on the cleaned injection site.
- **Do not** inject HYMPAVZI into bony areas or areas on your skin that are bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks.
- **Do not** inject HYMPAVZI into a vein.
- **Do not** inject HYMPAVZI through your clothes.

Step  
5

### Twist Off Cap



- **Twist and pull** off the cap.
- **Put** the cap into an FDA-cleared sharps container right away. You will not need it again.

**Note:**

- It is normal to see a few drops of medicine at the needle tip.
- The needle cover will stay inside the cap after cap removal.

**Caution:** Handle the pen with care as it contains a needle.

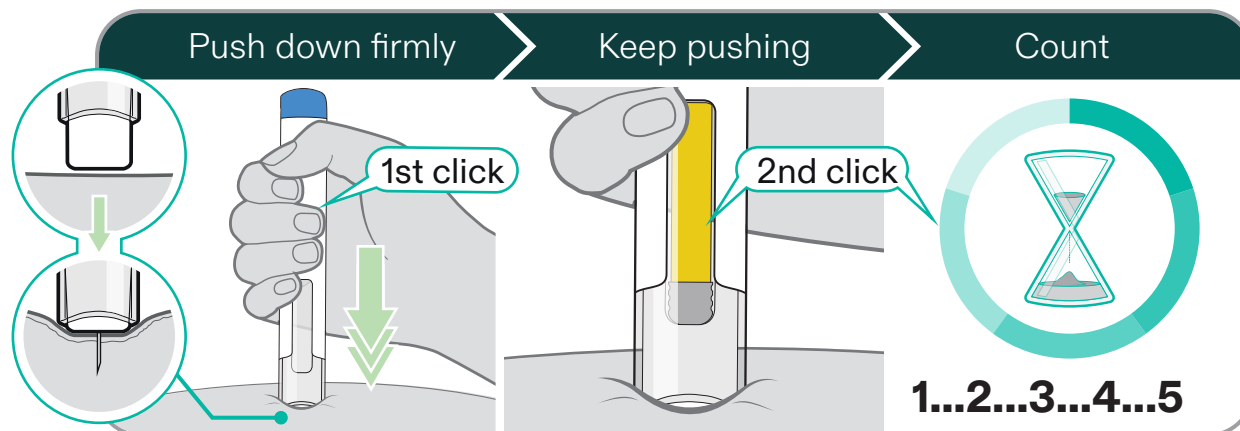
**Do not** put or press your hand over the needle guard. Doing so may cause a needle injury.

Please see full Important Safety Information at the end and full Prescribing Information, including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

# Injecting HYMPAVZI

Step  
6

## Inject Medicine



- **Hold** the pen straight (at 90° angle) against your cleaned skin so you can see the window.
- **Push** the pen **down firmly** straight against your skin and **keep pushing** until the injection is complete. You will hear the **1st click** when the injection starts.
- **Keep pushing** the pen firmly against your skin while the yellow bar moves across the window. You will hear a **2nd click** when the injection is **almost** complete.
- **Count slowly to 5** after you hear the **2nd click** to make sure you get a full dose.

**Do not remove the pen from your skin until you have counted slowly to 5 after you hear the 2nd click and until the yellow marker completely fills the window (see “Step 7 – Remove Pen”).**

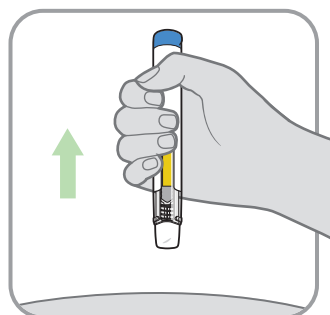
**Note:** The needle goes into your skin as you push the pen down. Your healthcare provider may suggest gently pinching your skin while you inject.

**Note:** If you do not hear a click when pushing the pen against your skin, try pushing down harder. If you still cannot start the injection, get a new HYMPAVZI prefilled pen.

**Caution:** If you change your mind where to inject after inserting the needle into your skin, you will need to throw away (dispose of) the pen and get a new HYMPAVZI prefilled pen.

Step  
7

## Remove Pen



- **Remove** the pen from your skin.
  - If you see a small drop of medicine on your skin, wait a little longer before removing the pen when you give your next injection.

**Note:** After you remove the pen from your skin, the needle guard will automatically cover the needle and lock in place.

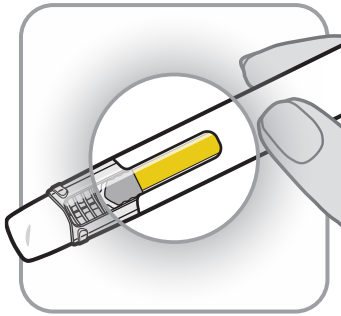
**The pen cannot be reused.**

Please see full Important Safety Information at the end and full Prescribing Information, including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

## Injecting HYMPAVZI (cont'd)

Step  
8

### Check Window



- **Check** the window to make sure all the medicine has been injected.

**If the yellow bar is not in the position shown, this means you have not received a full dose. Call your healthcare provider for help.**

**Do not inject another dose.**

Step  
9

### After Care



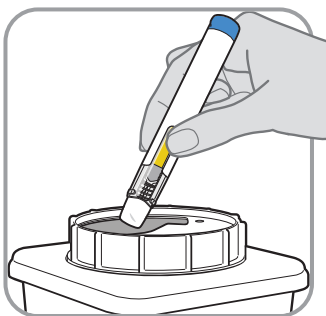
- **Press** lightly on the injection site for a few seconds with a clean cotton ball or gauze pad if you see a drop of blood.
- **Do not** rub the area.

**Note:** If bleeding does not stop, contact your healthcare provider.

**Note:** If your prescribed dose requires 2 injections of HYMPAVZI, repeat steps 1-9. Change (rotate) the injection site each time you give yourself an injection of HYMPAVZI. You may use the same area of your body but be sure to choose a different injection site in that area.

Step  
10

### Disposal of Pen



- **Put** the used pen in an FDA-cleared sharps disposal container right away after use.
- **Do not** throw away (dispose of) pens in the household trash.

**Note:** If you do not have an FDA-cleared sharps disposal container, please see the **“Safe Pen Disposal”** information section.

Please see full Important Safety Information at the end and full [Prescribing Information](#), including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).

# Safe Pen Disposal

- **Always throw away** (dispose of) pens in a sharps disposal container. **Do not** dispose of pens in the 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,
  - is upright and stable during use,
  - is leak-resistant, and
  - is 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 throw away (dispose of) your sharps disposal container. There may be state or local laws about how you should throw away used needles and pens. For more information about safe sharps disposal, and for specific information about safe sharps disposal for the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** recycle your used sharps disposal container.

## What is HYMPAVZI?

HYMPAVZI is a prescription medicine used to prevent or reduce the frequency of bleeding episodes in adults and children 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors.

It is not known if HYMPAVZI is safe and effective in children younger than 12 years old.

## IMPORTANT SAFETY INFORMATION

**Important: Before you start using HYMPAVZI, it is very important to talk to your healthcare provider about using factor VIII and factor IX products** (products that help blood clot but work in a different way than HYMPAVZI). You may need to use factor VIII or factor IX medicines to treat episodes of breakthrough bleeding during treatment with HYMPAVZI. Carefully follow your healthcare provider's instructions regarding when to use factor VIII or factor IX medicines and the prescribed dose during your treatment with HYMPAVZI.

**Before using HYMPAVZI, tell your healthcare provider about all of your medical conditions, including if you:**

- have a planned surgery. Your healthcare provider may stop treatment with HYMPAVZI before your surgery. Talk to your healthcare provider about when to stop using HYMPAVZI and when to start it again if you have a planned surgery.
- have a severe short-term (acute) illness such as an infection or injury.
- are pregnant or plan to become pregnant. HYMPAVZI may harm your unborn baby.

### Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start your treatment with HYMPAVZI.
- You should use effective birth control (contraception) during treatment with HYMPAVZI and for at least 2 months after the last dose of HYMPAVZI.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with HYMPAVZI.
- are breastfeeding or plan to breastfeed. It is not known if HYMPAVZI passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

## What are the possible side effects of HYMPAVZI?

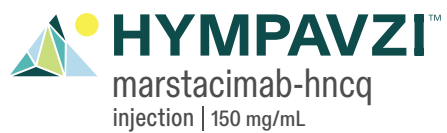
**HYMPAVZI may cause serious side effects, including:**

- **blood clots (thromboembolic events).** HYMPAVZI may increase the risk for your blood to clot. Blood clots may form in blood vessels in your arm, leg, lung, or head and can be life-threatening. Get medical help right away if you develop any of these signs or symptoms of blood clots: swelling or pain in arms or legs; redness or discoloration in your arms or legs; shortness of breath; pain in chest or upper back; fast heart rate; cough up blood; feel faint; headache; numbness in your face; eye pain or swelling; trouble seeing
- **allergic reactions.** Allergic reactions, including rash and itching have happened in people treated with HYMPAVZI. Stop using HYMPAVZI and get medical help right away if you develop any of the following symptoms of a severe allergic reaction: swelling of your face, lips, mouth, or tongue; trouble breathing; wheezing; dizziness or fainting; fast heartbeat or pounding in your chest; sweating

**The most common side effects of HYMPAVZI are injection site reactions, headache, and itching.**

These are not all the possible side effects of HYMPAVZI. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

**Please see full Prescribing Information, including Patient Information and Instructions for Use, at [www.HYMPAVZI.com](http://www.HYMPAVZI.com).**



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