

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PYZCHIVA**<sup>™</sup>

Piz-chi-va

ustekinumab injection

Solution for Subcutaneous Injection

Read this carefully before you start taking **PYZCHIVA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PYZCHIVA**.

PYZCHIVA is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA<sup>®</sup>. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

#### What is **PYZCHIVA** used for?

- **Adults with Plaque Psoriasis**

PYZCHIVA is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

PYZCHIVA is a prescription medicine that is approved for children and adolescent patients 6 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

- **Adults with Psoriatic Arthritis**

PYZCHIVA is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given PYZCHIVA by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking and climbing stairs) and improve your psoriasis.

- **Adults with Crohn's disease or ulcerative colitis**

PYZCHIVA/PYZCHIVA I.V. is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease and for adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, PYZCHIVA I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of PYZCHIVA are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given PYZCHIVA/PYZCHIVA I.V. to help relieve your symptoms and keep the disease under control. PYZCHIVA/PYZCHIVA I.V. may help reduce or stop the use of your corticosteroid

medication.

### **How does PYZCHIVA work?**

PYZCHIVA blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

### **What are the ingredients in PYZCHIVA?**

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: histidine, histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

### **PYZCHIVA comes in the following dosage forms:**

#### **Pre-filled Syringe:**

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

#### **Pre-filled Pen:**

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

#### **Single-use Vial:**

- 45 mg / 0.5 mL

### **Do not use PYZCHIVA if:**

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to PYZCHIVA, PYZCHIVA I.V., or any of the other ingredients in PYZCHIVA. See below for a complete list of ingredients in PYZCHIVA.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine while taking PYZCHIVA.

If you used PYZCHIVA while pregnant, tell your baby's healthcare professional about your PYZCHIVA use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

Always keep medicine out of the reach of children.

### **To help avoid side effects and ensure proper use, talk to your healthcare professional**

**before you take PYZCHIVA. Talk about any health conditions or problems you may have, including if you:**

- ever had an allergic reaction to PYZCHIVA or PYZCHIVA I.V. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received “allergy shots”, especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. PYZCHIVA may pass into your breast milk in small amounts.

**Contact your healthcare professional immediately:**

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with ustekinumab in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting PYZCHIVA and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use PYZCHIVA.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

**The following may interact with PYZCHIVA:**

- PYZCHIVA may change the way the body responds to live vaccines.
- PYZCHIVA may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your healthcare provider.

## How to take PYZCHIVA:

### **Instructions for injecting PYZCHIVA under the skin yourself:**

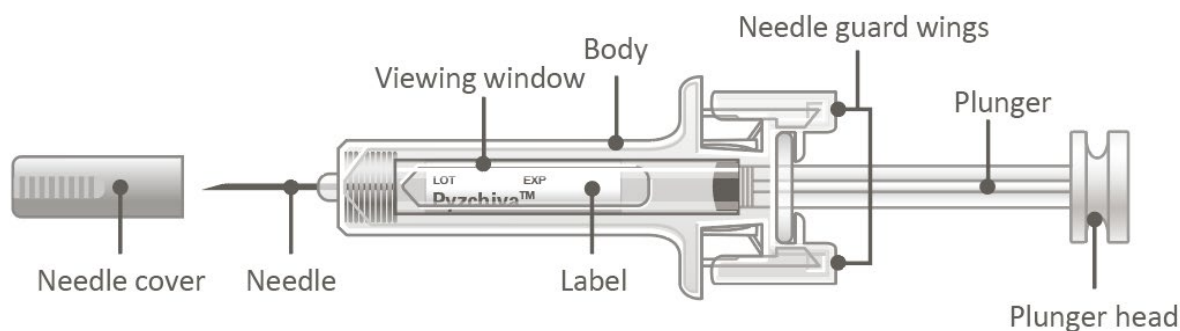
PYZCHIVA may be injected by your healthcare provider. In children 6 to 17 years of age, it is recommended that all doses of PYZCHIVA be administered by a health care provider. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject PYZCHIVA under the skin (subcutaneously) yourself. Before you self-inject PYZCHIVA, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. PYZCHIVA is not to be mixed with other liquids for injection.

### **INSTRUCTIONS FOR INJECTING PYZCHIVA USING A PRE-FILLED SYRINGE**

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake PYZCHIVA at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

#### **1: PREPARING FOR PRE-FILLED SYRINGE USE**



#### **Take the Syringe out of the Refrigerator**

Take the pre-filled syringe(s) out of the refrigerator. Let the pre-filled syringe stand outside the box for about half an hour. This will let the liquid come to a comfortable temperature for injection (room temperature). Do not warm the pre-filled syringe in any other way (for example, do not warm it in a microwave or in hot water.). Do not remove the syringe's needle cover while allowing it to reach room temperature.

If your dose amount is 90 mg and you receive two 45 mg packages, you need to give a second injection right after the first. Choose a different site for the second injection.

#### **Check Expiration Date**

Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, or if the pre-filled syringe has been kept at room temperature up to 30°C for longer than 35 days or if the pre-filled syringe has been stored above 30°C, DO NOT use the pre-filled syringe.

#### **Assemble Additional Supplies**

Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

### **Check Solution in Syringe**

Hold the pre-filled syringe with the covered needle pointing upward. Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear, colourless to light yellow. DO NOT use if it is frozen, discoloured, cloudy or contains particles and contact your healthcare provider for assistance.

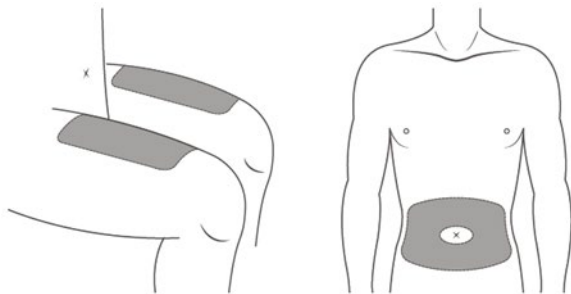
**DO NOT** remove the needle cover from the pre-filled syringe.

**DO NOT** pull back on the plunger head at any time.

## **2: CHOOSING AND PREPARING THE INJECTION SITE**

### **Choose the Injection Site\***

Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



\*Areas in gray are recommended injection sites.

### **Prepare the Injection Site**

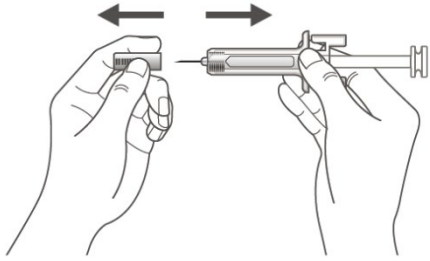
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

## **3: INJECTING THE MEDICATION**

### **Remove the Needle Cover**

When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should NOT be removed until you are ready to inject the dose. Do not use syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your healthcare provider for assistance.



### **Inject the Medication**

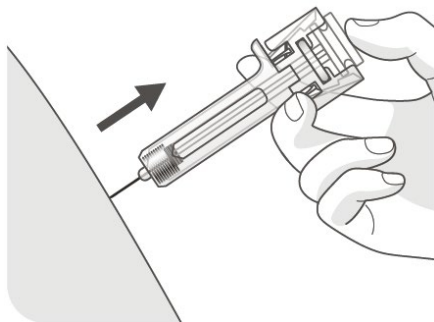
Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it. Push the syringe needle into the pinched skin.



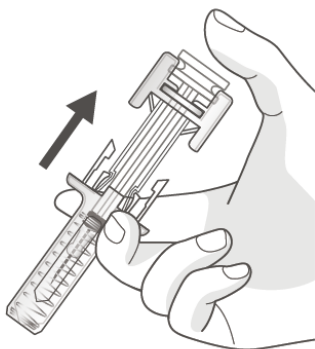
Push the plunger with your thumb as far as it will go to inject all of the liquid.

Push it slowly and evenly, keeping the skin pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle.



Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.



#### 4: AFTER THE INJECTION

##### Dispose of the Empty Syringe

Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations.



##### Use a Cotton Ball or Gauze

There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

## INSTRUCTIONS FOR INJECTING PYZCHIVA USING A 45 mg/0.5 mL PRE-FILLED PEN

Read this Instructions for Use before you start using PYZCHIVA. Your healthcare professional should show you how to prepare and give your injection of PYZCHIVA the right way.

If you cannot give yourself the injection:

- ask your healthcare professional to help you, or
- ask someone who has been trained by a healthcare professional to give your injections.

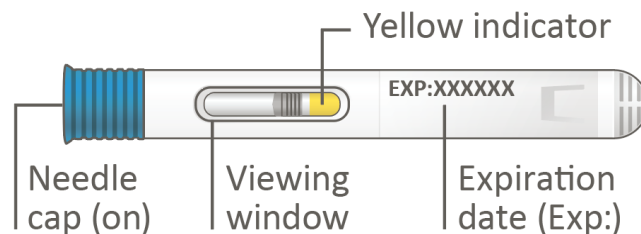
**Do not** try to inject PYZCHIVA yourself until you have been shown how to inject PYZCHIVA by your health professional.

### Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

### Guide to parts:

#### Before use



#### After use

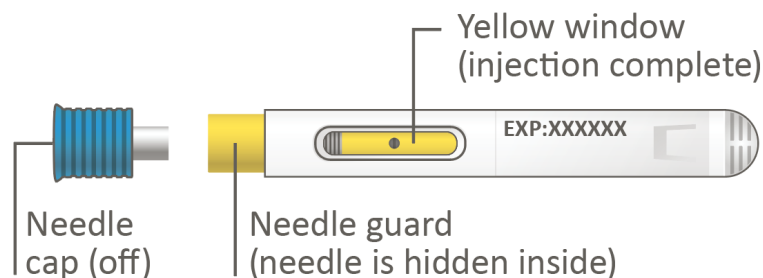


Figure A

### Important information You Need to Know Before Injecting PYZCHIVA

- **For subcutaneous injection only** (inject directly under the skin)
- **Do not** remove the needle cap before you are ready to inject.
- **Do not shake the pre-filled pen at any time.** Shaking your pre-filled pen may damage your PYZCHIVA medicine.

### Storing PYZCHIVA pre-filled pen:

- Store PYZCHIVA in the refrigerator between 2°C to 8°C.
- Store PYZCHIVA in the original carton to protect from light or physical damage.
- If needed, individual PYZCHIVA pre-filled pens may also be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the

original carton with protection from light. Record the date when the pre-filled pen is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. At the end of this period the product can be placed back to the refrigerator for up to 60 days at 2-8°C as an optional secondary storage condition. Discard the pen if not used within 35 days at room temperature storage and 60 days of optional secondary storage back in the refrigerator or by the original expiry date, whichever is earlier. **Do not** store PYZCHIVA in extreme heat or cold.

- **Do not** freeze.

## Preparing to Inject PYZCHIVA pre-filled pen

**Step 1 Before you start, check the carton to make sure that it is the right dose.** You will have either 45 mg or 90 mg as prescribed by your doctor.

- If your dose is 45 mg, you will receive one 45 mg pre-filled pen.
- If your dose is 90 mg, you will receive either one 90 mg pre-filled pen or two 45 mg pre-filled pens. If you receive two 45 mg pre-filled pens for a 90 mg dose, you will need to give yourself two injections, one right after the other.

## Step 2 Gather supplies

- **Step 2.1:** Choose a well-lit, clean, flat work surface.
- **Step 2.2:** Gather the supplies you will need to prepare and to give your injection (**Figure B**).
- You will need the following supplies.
  - Included in the carton:
    - PYZCHIVA pre-filled pen
  - Not included in the carton:
    - Alcohol swab
    - Cotton balls or gauze pads
    - Adhesive bandage
    - Sharps disposal container (**See "Disposing of PYZCHIVA pre-filled pen."**)

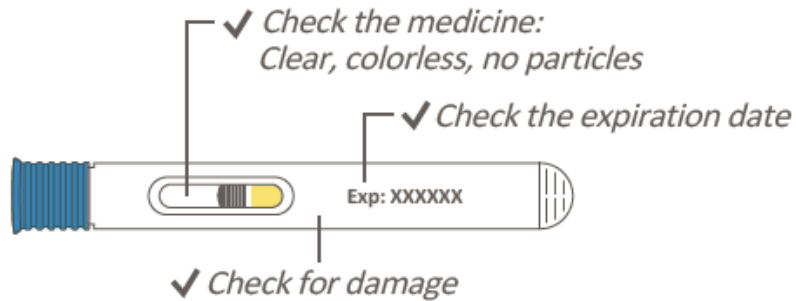


**Figure B**

## Step 3 Inspect the pre-filled pen (Figure C)

- **Step 3.1:** Check the expiration date on the pre-filled pen or carton.
- **Step 3.2:** Check the medicine in the viewing window for any particles or discoloration. The medicine should look clear, colourless to light yellow.
- **Step 3.3:** Make sure the pen is not damaged.
- **Do not** use PYZCHIVA if:
  - the expiration date has passed or if the pre-filled pen has been kept at room temperature up to 30°C for longer than a maximum single period of 35 days or if the pre-filled pen has been stored above 30°C.
  - it is frozen, discolored, cloudy or has large particles.
  - it is damaged.
  - it is dropped and appears cracked or broken.

- It is normal to see 1 or more bubbles in the window.



**Figure C**

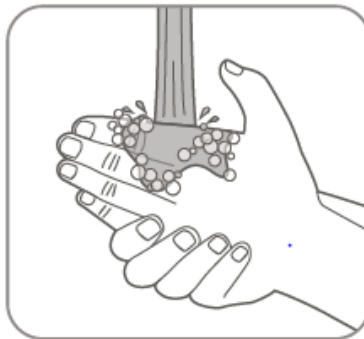
**Step 4 Allow the medicine to reach room temperature**

- For a more comfortable injection, leave PYZCHIVA pre-filled pen at room temperature for about 30 minutes before injecting, after removing it from the refrigerator.
- **Do not** warm the pre-filled pen in any other way (for example, do not warm it in a microwave or in hot water).



**Step 5 Wash your hands**

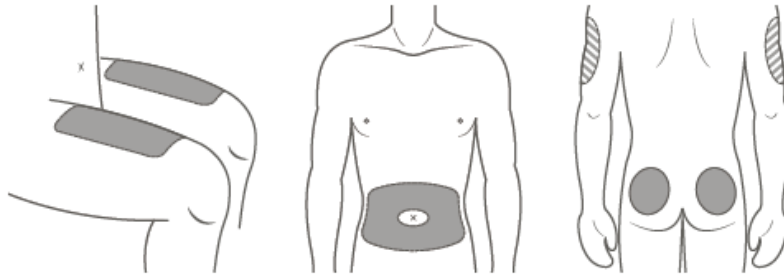
- Wash your hands well with soap and warm water (**Figure D**).



**Figure D**

**Step 6 Choose the injection site**

- Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. (**Figure E**)
- **Use a different injection site for each injection.**
- **Do not** give an injection in an area of the skin that is tender, bruised, red, or hard or shows signs of psoriasis.

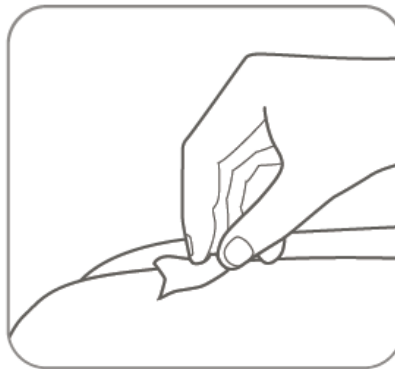


**Figure E**

\*Areas in gray are recommended injection sites.

**Step 7 Clean the skin at the injection site**

- Clean the skin with a new alcohol swab where you plan to give your injection. **(Figure F)**
- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.

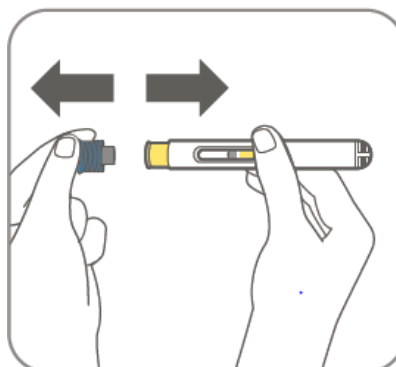


**Figure F**

**Injecting PYZCHIVA pre-filled pen**

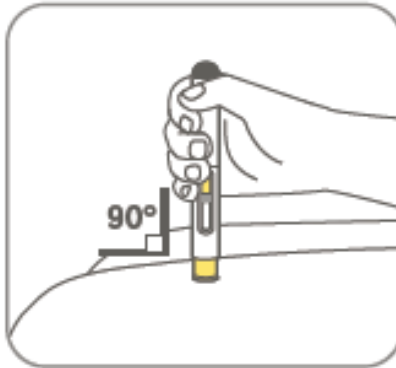
**Step 8 Pull the needle cap straight off when you are ready to inject your PYZCHIVA (Figure G).**

- Throw away the needle cap.
- It is normal to see a few drops of liquid come out of the needle.
- **Do not** twist or bend the needle cap while removing it, as this may damage the needle.
- **Do not** use the pre-filled pen if it is dropped after removing the needle cap. Call your health professional for instructions.



**Figure G**

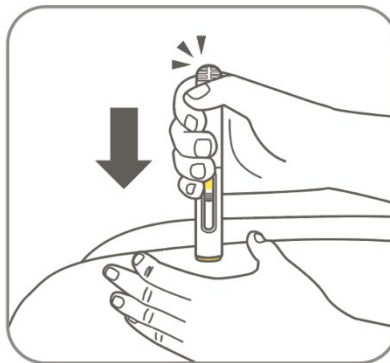
**Step 9 Position the pre-filled pen straight on your skin at 90 degrees (Figure H).**



**Figure H**

**Step 10 Firmly push the pre-filled pen down onto the skin to start the injection (Figure I).**

- You may hear a first click when the injection begins.

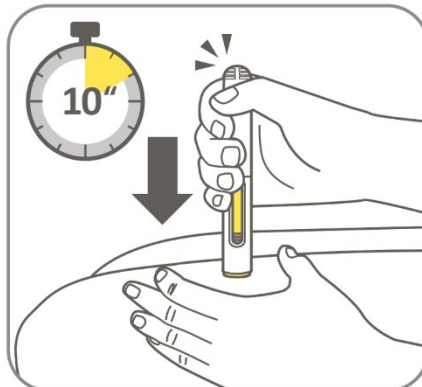


**Figure I**

**Step 11 Continue to press down onto the skin until the yellow indicator stops moving (Figure J).**

Your injection could take up to **10 seconds**.

- You may hear a second click. This means the injection is finished.
- **Do not** release pressure against the injection site before the injection is complete.
- **Do not** move the pre-filled pen during the injection.

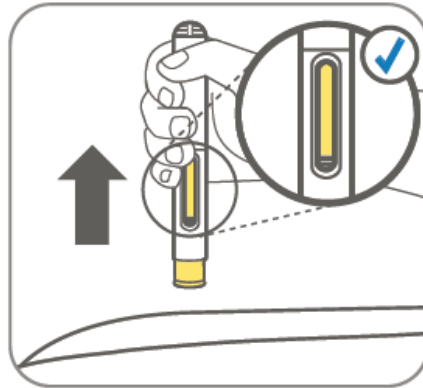


**Figure J**

**Step 12 Check that the viewing window has turned yellow to make sure the full dose has been delivered and remove the empty pen from your skin (Figure K).**

- The needle guard will completely cover the needle.

- As in **Figure K**, a small gray band may still be visible in the viewing window.
- When the needle is pulled out of your skin, there may be a little bleeding or a few drops at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.



**Figure K**

**If your dose is 90 mg, you will receive either one 90 mg pre-filled pen or two 45 mg pre-filled pens. If you receive two 45 mg pre-filled pens for a 90 mg dose, you will need to give yourself a second injection right after the first. Repeat Steps 1–12 for the second injection using a new pen. Choose a different site for the second injection.**

#### **Disposing of PYZCHIVA pre-filled pen**

**Step 13 Put the used pen in a sharps disposal container right away after use (Figure L).**

- **Do not** throw away (dispose of) loose pens in your household trash.
- **Do not** recycle your used sharps disposal container.



**Figure L**

**Keep PYZCHIVA and all medicines out of the reach of children.**

## INSTRUCTIONS FOR INJECTING PYZCHIVA USING A 90 mg/1.0 mL PRE-FILLED PEN

Read this Instructions for Use before you start using PYZCHIVA. Your healthcare professional should show you how to prepare and give your injection of PYZCHIVA the right way.

If you cannot give yourself the injection:

- ask your healthcare professional to help you, or
- ask someone who has been trained by a healthcare professional to give your injections.

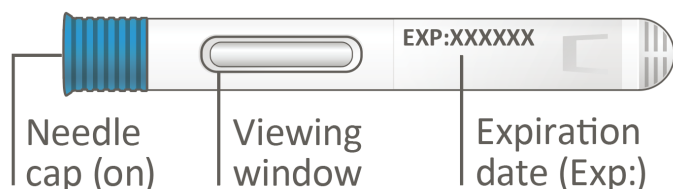
**Do not** try to inject PYZCHIVA yourself until you have been shown how to inject PYZCHIVA by your health professional.

### Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

### Guide to parts:

#### Before use



#### After use

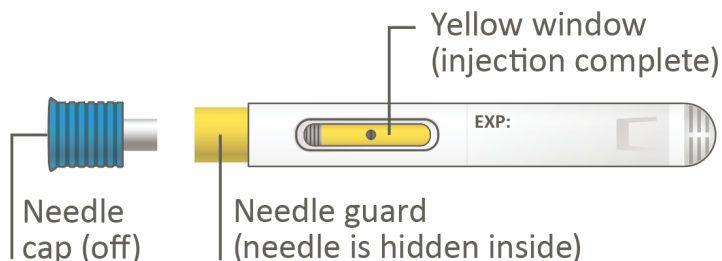


Figure A

### Important information You Need to Know Before Injecting PYZCHIVA

- **For subcutaneous injection only** (inject directly under the skin)
- **Do not** remove the needle cap before you are ready to inject.
- **Do not shake the pre-filled pen at any time.** Shaking your pre-filled pen may damage your PYZCHIVA medicine.

### Storing PYZCHIVA pre-filled pen:

- Store PYZCHIVA in the refrigerator between 2°C to 8°C.
- Store PYZCHIVA in the original carton to protect from light or physical damage.
- If needed, individual PYZCHIVA pre-filled pens may also be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton with protection from light. Record the date when the pre-filled pen is

first removed from the refrigerator and the new expiry date on the carton in the spaces provided. At the end of this period the product can be placed back to the refrigerator for up to 60 days at 2-8°C as an optional secondary storage condition. Discard the pen if not used within 35 days at room temperature storage and 60 days of optional secondary storage back in the refrigerator or by the original expiry date, whichever is earlier. **Do not** store PYZCHIVA in extreme heat or cold.

- **Do not** freeze.

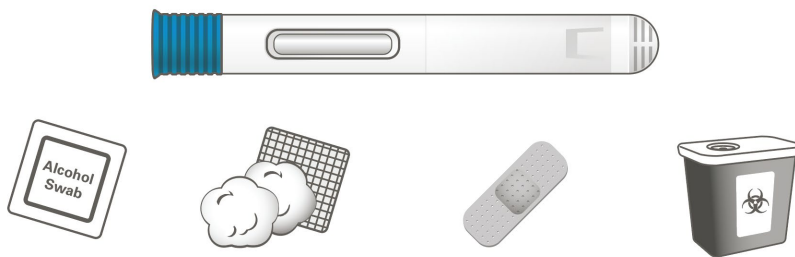
## Preparing to Inject PYZCHIVA pre-filled pen

**Step 1 Before you start, check the carton to make sure that it is the right dose.** You will have either 45 mg or 90 mg as prescribed by your doctor.

- If your dose is 45 mg, you will receive one 45 mg pre-filled pen.
- If your dose is 90 mg, you will receive either one 90 mg pre-filled pen or two 45 mg pre-filled pens. If you receive two 45 mg pre-filled pens for a 90 mg dose, you will need to give yourself two injections, one right after the other.

## Step 2 Gather supplies

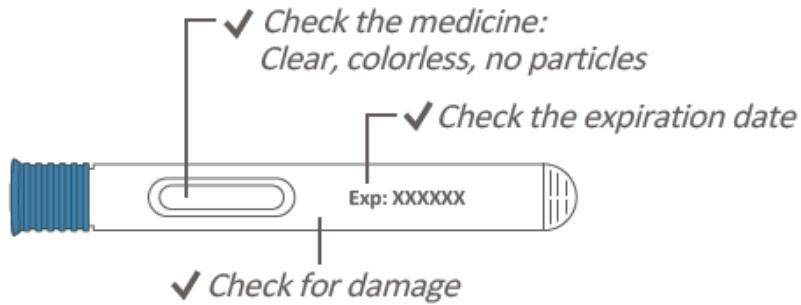
- **Step 2.1:** Choose a well-lit, clean, flat work surface.
- **Step 2.2:** Gather the supplies you will need to prepare and to give your injection (**Figure B**).
- You will need the following supplies.
  - Included in the carton:
    - PYZCHIVA pre-filled pen
  - Not included in the carton:
    - Alcohol swab
    - Cotton balls or gauze pads
    - Adhesive bandage
    - Sharps disposal container (**See "Disposing of PYZCHIVA pre-filled pen."**)



**Figure B**

## Step 3 Inspect the pre-filled pen (Figure C)

- **Step 3.1:** Check the expiration date on the pre-filled pen or carton.
- **Step 3.2:** Check the medicine in the viewing window for any particles or discoloration. The medicine should look clear, colourless to light yellow.
- **Step 3.3:** Make sure the pen is not damaged.
- **Do not** use PYZCHIVA if:
  - the expiration date has passed or if the pre-filled pen has been kept at room temperature up to 30°C for longer than a maximum single period of 35 days or if the pre-filled pen has been stored above 30°C.
  - it is frozen, discolored, cloudy or has large particles.
  - it is damaged.
  - it is dropped and appears cracked or broken.
- It is normal to see 1 or more bubbles in the window.



**Figure C**

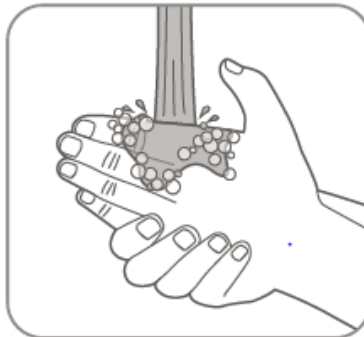
**Step 4 Allow the medicine to reach room temperature**

- For a more comfortable injection, leave PYZCHIVA pre-filled pen at room temperature for about 30 minutes before injecting, after removing it from the refrigerator.
- **Do not** warm the pre-filled pen in any other way (for example, do not warm it in a microwave or in hot water).



**Step 5 Wash your hands**

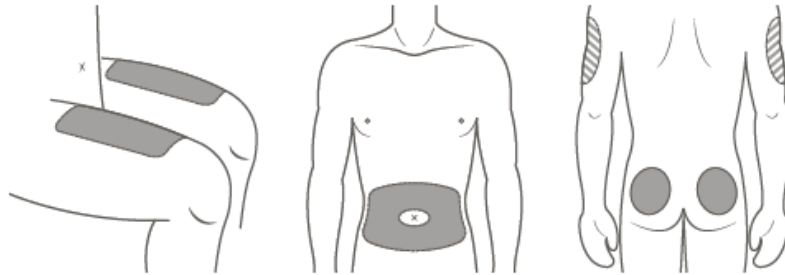
- Wash your hands well with soap and warm water (**Figure D**).



**Figure D**

**Step 6 Choose the injection site**

- Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. (**Figure E**)
- **Use a different injection site for each injection.**
- **Do not** give an injection in an area of the skin that is tender, bruised, red, or hard or shows signs of psoriasis.

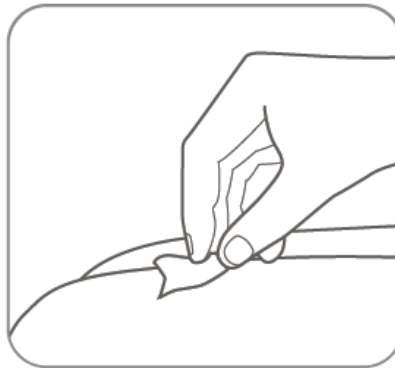


\*Areas in gray are recommended injection sites.

**Figure E**

**Step 7 Clean the skin at the injection site**

- Clean the skin with a new alcohol swab where you plan to give your injection. **(Figure F)**
- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.

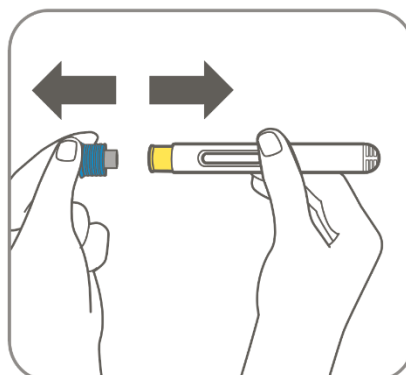


**Figure F**

**Injecting PYZCHIVA pre-filled pen**

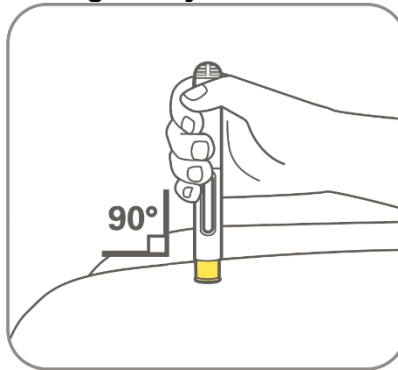
**Step 8 Pull the needle cap straight off when you are ready to inject your PYZCHIVA (Figure G).**

- Throw away the needle cap.
- It is normal to see a few drops of liquid come out of the needle.
- **Do not** twist or bend the needle cap while removing it, as this may damage the needle.
- **Do not** use the pre-filled pen if it is dropped after removing the needle cap. Call your health professional for instructions.



**Figure G**

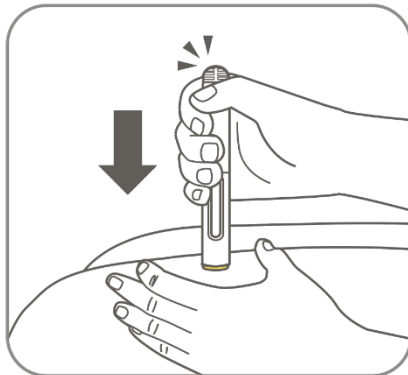
**Step 9 Position the pre-filled pen straight on your skin at 90 degrees (Figure H).**



**Figure H**

**Step 10 Firmly push the pre-filled pen down onto the skin to start the injection (Figure I).**

- You may hear a first click when the injection begins.

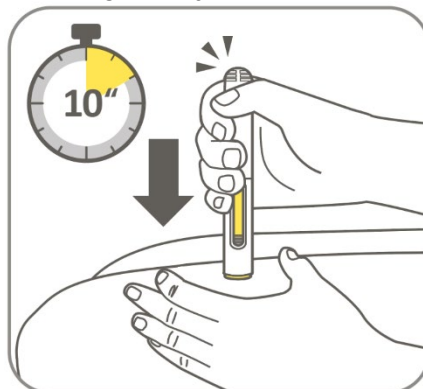


**Figure I**

**Step 11 Continue to press down onto the skin until the yellow indicator stops moving. (Figure J).**

Your injection could take up to **10 seconds**.

- You may hear a second click. This means the injection is finished.
- **Do not** release pressure against the injection site before the injection is complete.
- **Do not** move the pre-filled pen during the injection.

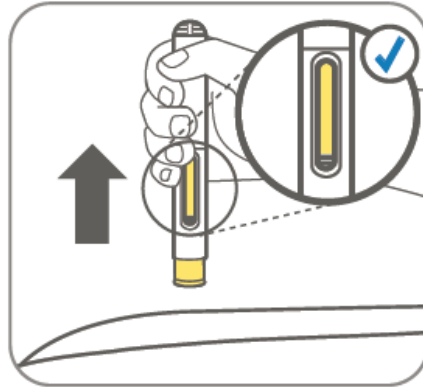


**Figure J**

**Step 12 Check that the viewing window has turned yellow to make sure the full dose has been delivered and remove the empty pen from your skin (Figure K).**

- The needle guard will completely cover the needle.

- As in **Figure K**, a small gray band may still be visible in the viewing window.
- When the needle is pulled out of your skin, there may be a little bleeding or a few drops at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.



**Figure K**

**If your dose is 90 mg, you will receive either one 90 mg pre-filled pen or two 45 mg pre-filled pens. If you receive two 45 mg pre-filled pens for a 90 mg dose, you will need to give yourself a second injection right after the first. Repeat Steps 1–12 for the second injection using a new pen. Choose a different site for the second injection.**

#### **Disposing of PYZCHIVA pre-filled pen**

**Step 13 Put the used pen in a sharps disposal container right away after use (Figure L).**

- **Do not** throw away (dispose of) loose pens in your household trash.
- **Do not** recycle your used sharps disposal container.



**Figure L**

**Keep PYZCHIVA and all medicines out of the reach of children.**

## INSTRUCTIONS FOR INJECTING PYZCHIVA FROM A 45 mg/0.5 mL VIAL

Do not shake PYZCHIVA Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. PYZCHIVA is not to be mixed with other liquids for injection.

### 1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

#### Take the Vial(s) out of the Refrigerator

If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

#### Check Expiration Date

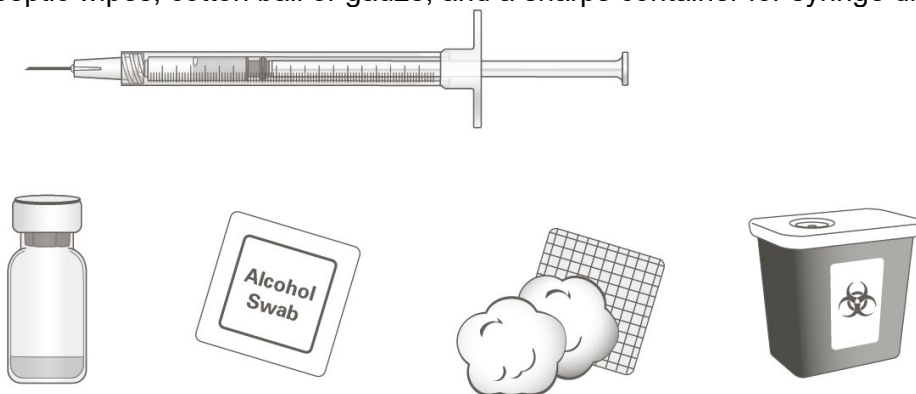
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

#### Check Solution in Vial

Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear, colourless to light yellow. **DO NOT** use if it is frozen, discoloured, cloudy or contains particles and contact your healthcare provider for assistance.

#### Assemble Additional Supplies

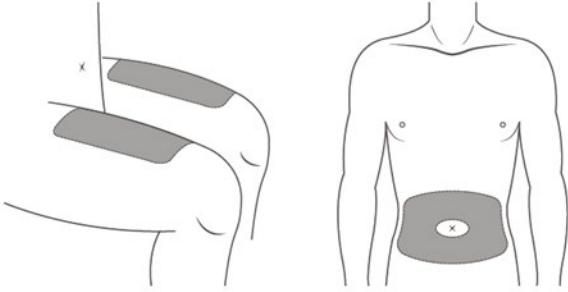
Assemble the additional supplies you will need for your injection. These include a syringe, needle, antiseptic wipes, cotton ball or gauze, and a sharps container for syringe disposal.



### 2: CHOOSING AND PREPARING THE INJECTION SITE

#### Choose the Injection Site\*

Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



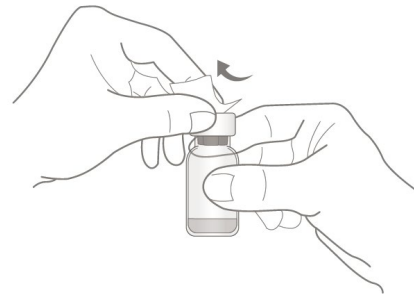
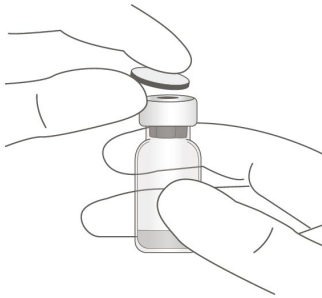
\*Areas in gray are recommended injection sites.

### **Prepare the Injection Site**

Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. **DO NOT** touch this area again before giving the injection.

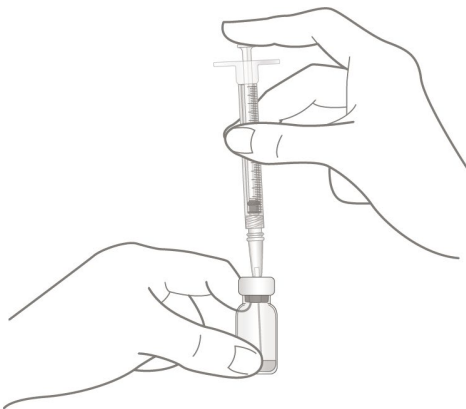
### **3: PREPARING THE DOSE**

Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.



**Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.**

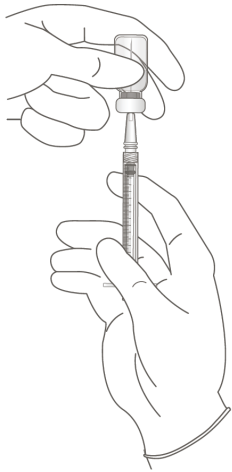
**Put the vial on a flat surface and push the syringe needle through the rubber stopper.**



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

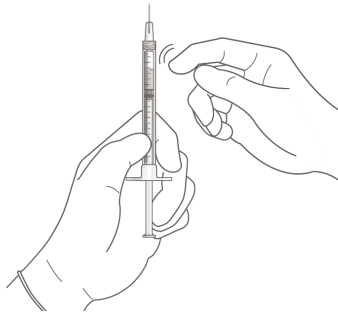
For adults and children 6 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider. It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.



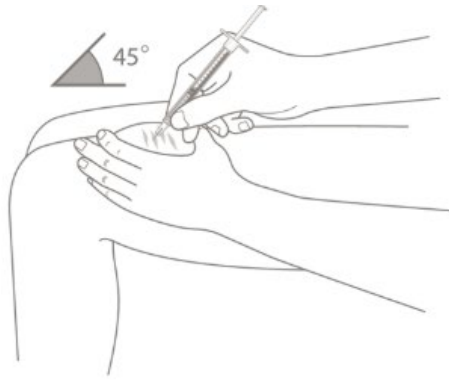
#### **Remove the needle from the vial**

Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



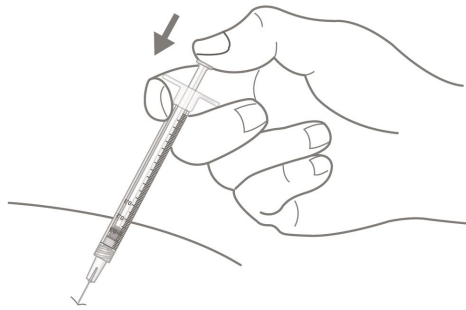
#### **4: INJECTING THE MEDICATION**

Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it



**Push the syringe needle into the pinched skin.**

**Push the plunger with your thumb as far as it will go to inject all of the liquid.** Push it slowly and evenly, keeping the skin gently pinched.



**When the plunger is pushed as far as it will go,** take out the needle and let go of the skin.

**Press an antiseptic wipe** over the injection site for a few seconds after the injection.

#### **Dispose the Empty Syringe and Vial(s)**

Discard any unused portion of PYZCHIVA in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

#### **Use a Cotton Ball or Gauze**

There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

**Usual dose:**Psoriasis

For treatment of psoriasis, PYZCHIVA is given by injection under the skin.

**Adults:**

The recommended dose of PYZCHIVA is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg.

**Pediatric Psoriasis (6 years of age or older):**

The recommended dose of PYZCHIVA based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of PYZCHIVA	Dosage Form
< 60 kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, pre-filled pen, vial
> 100 kg	90 mg	Pre-filled syringe, pre-filled pen

\* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31

38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 of age with psoriasis, it is recommended that PYZCHIVA be administered by a health care provider. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer PYZCHIVA to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the **“Instructions for injecting PYZCHIVA under the skin yourself”**.)

#### Psoriatic Arthritis

For treatment of psoriatic arthritis, PYZCHIVA is given by injection under the skin. The recommended dose of PYZCHIVA is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

#### Crohn’s disease and ulcerative colitis

For treatment of Crohn’s disease or ulcerative colitis, the recommended dose is a single intravenous dose of PYZCHIVA I.V. based on body weight (as shown below) followed by 90 mg PYZCHIVA given by injection under the skin (subcutaneous).

<b>Weight</b>	<b>Recommended Dose of PYZCHIVA I.V.</b>
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn’s disease and ulcerative colitis is as follows:

<b>Treatment number</b>	<b>Time of treatment</b>	<b>Route of administration</b>
-------------------------	--------------------------	--------------------------------

Treatment 1	Week 0 Intravenous infusion (PYZCHIVA I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (PYZCHIVA)
Further treatment	Every 8 weeks* Subcutaneous injection (PYZCHIVA)

\* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

### Overdose:

Call your healthcare professional if you accidentally inject PYZCHIVA more frequently than instructed.

If you think you, or a person you are caring for, have taken too much PYZCHIVA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### Missed dose:

If you miss a dose, contact your healthcare provider for guidance.

### What are possible side effects from using PYZCHIVA?

These are not all the possible side effects you may have when taking PYZCHIVA. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of PYZCHIVA are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

PYZCHIVA is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

#### Serious Infections

- PYZCHIVA may lower your ability to fight infections. Some infections could become

serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using PYZCHIVA. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.

- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with PYZCHIVA and during treatment with PYZCHIVA.

#### Cancers

- PYZCHIVA may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving PYZCHIVA treatment.

#### Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON (&gt;10%)</b>			
Infected nose, sinuses or throat (cold)	✓		
<b>COMMON (≥1% and &lt;10%)</b>			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
<b>UNCOMMON (≥0.1% and &lt;1%)</b>			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
<b>RARE (≥0.01% and &lt;0.1%)</b>			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

In general, the side effects of PYZCHIVA seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## Storage:

If you are using PYZCHIVA at home, it is important to store the product in your refrigerator at 2-8°C although not in the freezer compartment. PYZCHIVA should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

If needed, individual PYZCHIVA pre-filled syringes and pre-filled pens may also be stored at room temperature up to 30°C for a maximum single period of up to 35 days in the original carton with protection from light. Record the date when the pre-filled syringe or pre-filled pen is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. At the end of this period the product can be placed back to the refrigerator for up to 60 days at 2-8°C as an optional secondary storage condition. Discard the syringe or pen if not used within 35 days at room temperature storage and 60 days of optional secondary storage back in the refrigerator or by the original expiry date, whichever is earlier.

Always keep medicine out of the reach and sight of children.

## If you want more information about PYZCHIVA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Canadian distributor (Organon Canada Inc.) website [www.organon.ca](http://www.organon.ca), or by 1-844-820-5468.

This leaflet was prepared by Samsung Bioepis Co., Ltd

Last revised: Nov 21, 2025

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr PYZCHIVA™ I.V.**

Piz-chi-va

ustekinumab for injection

Solution for Intravenous Infusion

Read this carefully before you start taking **PYZCHIVA I.V.** This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PYZCHIVA I.V.**

PYZCHIVA is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

#### **What is PYZCHIVA I.V. used for?**

- **Adults with Crohn's disease or ulcerative colitis**

PYZCHIVA I.V./PYZCHIVA is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease or adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, PYZCHIVA I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of PYZCHIVA are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given PYZCHIVA I.V./PYZCHIVA to help relieve your symptoms and keep the disease under control. PYZCHIVA I.V./ PYZCHIVA may help reduce or stop the use of your corticosteroid medication.

#### **How does PYZCHIVA I.V. work?**

PYZCHIVA I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease and ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the digestive tract.

#### **What are the ingredients in PYZCHIVA I.V.?**

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: histidine and histidine hydrochloride monohydrate, methionine, disodium edetate, polysorbate 80, sucrose and water for injection. No preservatives are present.

#### **PYZCHIVA I.V. comes in the following dosage forms:**

PYZCHIVA I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg

ustekinumab in 26 mL.

**Do not use PYZCHIVA I.V. if:**

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to PYZCHIVA I.V. or PYZCHIVA or any of the other ingredients in PYZCHIVA I.V. See below for a complete list of ingredients in PYZCHIVA I.V.
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine when taking PYZCHIVA I.V.

If you used PYZCHIVA I.V. while pregnant, tell your baby's healthcare professional about your PYZCHIVA I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PYZCHIVA I.V. Talk about any health conditions or problems you may have, including if you:**

- ever had an allergic reaction to PYZCHIVA I.V. or PYZCHIVA. Ask your healthcare professional if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding. PYZCHIVA I.V. may pass into your breast milk in small amounts.

**Contact your healthcare professional immediately:**

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with ustekinumab in pregnant and breastfeeding women. If you are a woman of childbearing potential, you should use effective contraception when starting PYZCHIVA I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breastfeeding, your healthcare professional will help you decide whether or not to use PYZCHIVA I.V./PYZCHIVA.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Know the medicines you take. Keep a list of your medicines and show them to your healthcare professionals when you get a new medicine.

**The following may interact with PYZCHIVA I.V.:**

- PYZCHIVA I.V. may change the way the body responds to live vaccines.
- PYZCHIVA I.V. may interact with other medications that decrease the activity of the immune system.

Your healthcare professional will assess your health before each treatment.

If you have questions, ask your healthcare provider.

**How to take PYZCHIVA I.V.:**

**Usual dose:**

Crohn's disease and ulcerative colitis

For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of PYZCHIVA I.V. based on body weight (as shown below) followed by 90 mg PYZCHIVA given by injection under the skin (subcutaneous).

<b>Weight</b>	<b>Recommended Dose of PYZCHIVA I.V.</b>
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

<b>Treatment number</b>	<b>Time of treatment Route of administration</b>
Treatment 1	Week 0 Intravenous infusion (PYZCHIVA I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (PYZCHIVA)
Further treatment	Every 8 weeks* Subcutaneous injection (PYZCHIVA)

\* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The initial dose of PYZCHIVA I.V. for intravenous infusion for Crohn's disease or ulcerative colitis will be given over a period of at least one hour.

**Overdose:**

In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse effects and appropriate symptomatic treatment be instituted immediately.

If you think you, or a person you are caring for, have taken too much PYZCHIVA I.V., contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using PYZCHIVA I.V.?**

These are not all the possible side effects you may have when taking PYZCHIVA. If you have any side effects not listed here, tell your healthcare professional.

The most common side effects of PYZCHIVA I.V. are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

PYZCHIVA I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

**Serious Infections**

- PYZCHIVA I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using PYZCHIVA I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with PYZCHIVA I.V.

**Cancers**

- PYZCHIVA I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving PYZCHIVA I.V. treatment.

### Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your healthcare professional immediately if you notice any of these signs.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON (&gt;10%)</b>			
Infected nose, sinuses or throat (cold)	✓		
<b>COMMON (≥1% and &lt;10%)</b>			
Sore throat, nasal congestion	✓		
Allergic reaction (skin rash)		✓	
<b>UNCOMMON (≥0.1% and &lt;1%)</b>			
Cellulitis (skin infection)		✓	
Vaginal yeast infections	✓		
Tooth abscess/tooth infection		✓	
<b>RARE (≥0.01% and &lt;0.1%)</b>			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			✓
Increase in redness and shedding of skin		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

PYZCHIVA I.V. must be stored in the original package in the refrigerator at 2-8°C before use. PYZCHIVA I.V. should not be frozen. Keep the product in its original carton to protect from light until the time of use. Do not shake. It must be kept out of the reach and sight of children.

Chemical and physical in-use stability of PYZCHIVA I.V. has been demonstrated for up to 1 month at 2°C to 8°C, followed by up to 72 hours at up to 30°C in 0.9% and 0.45% sodium chloride solution. From a microbiological point of view, the infusion solution should be administered immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8 °C unless dilution has taken place in controlled and validated aseptic conditions.

**If you want more information about PYZCHIVA I.V.:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the Canadian distributor (Organon Canada Inc.) website [www.organon.ca](http://www.organon.ca), or by 1-844-820-5468.

This leaflet was prepared by Samsung Bioepis Co., Ltd

Last revised: Nov 21, 2025