Package leaflet: Information for the user

Pyzchiva 90 mg solution for injection in pre-filled pen
ustekinumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This leaflet has been written for the person taking the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pyzchiva is and what it is used for
2. What you need to know before you use Pyzchiva
3. How to use Pyzchiva
4. Possible side effects
5. How to store Pyzchiva
6. Contents of the pack and other information

1. What Pyzchiva is and what it is used for

What Pyzchiva is
Pyzchiva contains the active substance ‘ustekinumab’, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

Pyzchiva belongs to a group of medicines called ‘immunosuppressants’. These medicines work by weakening part of the immune system.

What Pyzchiva is used for
Pyzchiva administered using the pre-filled pen is used to treat the following inflammatory diseases:
- Plaque psoriasis - in adults
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis
Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails. Pyzchiva will reduce the inflammation and other signs of the disease.

Pyzchiva administered using the pre-filled pen is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well

enough to these medicines, you may be given Pyzchiva to:
- Reduce the signs and symptoms of your disease.
- Improve your physical function.
- Slow down the damage to your joints.

Crohn's disease
Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Pyzchiva to reduce the signs and symptoms of your disease.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Pyzchiva to reduce the signs and symptoms of your disease.

2. What you need to know before you use Pyzchiva

Do not use Pyzchiva
- **If you are allergic to ustekinumab** or any of the other ingredients of this medicine (listed in section 6).
- **If you have an active infection** which your doctor thinks is important.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Pyzchiva.

Warnings and precautions
Talk to your doctor or pharmacist before using Pyzchiva. Your doctor will check how well you are before each treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have Pyzchiva. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects
Pyzchiva can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking Pyzchiva. See 'Serious side effects' in section 4 for a full list of these side effects.

Before you use Pyzchiva tell your doctor:
- **If you ever had an allergic reaction to Pyzchiva**. Ask your doctor if you are not sure.
- **If you have ever had any type of cancer** – this is because immunosuppressants like Pyzchiva weaken part of the immune system. This may increase the risk of cancer.
- **If you have been treated for psoriasis with other biologic medicines (a medicine produced from a biological source and usually given by injection)** – the risk of cancer may be higher.
- **If you have or have had a recent infection**.
- **If you have any new or changing lesions** within psoriasis areas or on normal skin.
- **If you are having any other treatment for psoriasis and/or psoriatic arthritis** – such as another immunosuppressant or phototherapy (when your body is treated with a type of ultraviolet (UV) light). These treatments may also weaken part of the immune system. Using these therapies together with Pyzchiva has not been studied. However it is possible it may increase the chance of diseases related to a weaker immune system.
- **If you are having or have ever had injections to treat allergies** – it is not known if Pyzchiva may affect these.
- **If you are 65 years of age or over** – you may be more likely to get infections.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Pyzchiva.

Some patients have experienced lupus-like reactions including skin lupus or lupus-like syndrome during treatment with ustekinumab. Talk to your doctor right away if you experience a red, raised, scaly rash sometimes with a darker border, in areas of the skin that are exposed to the sun or with joint pains.

Heart attack and strokes
Heart attack and strokes have been observed in a study in patients with psoriasis treated with Pyzchiva. Your doctor will regularly check your risk factors for heart disease and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or abnormal sensation on one side of your body, facial droop, or speech or visual abnormalities.

Children and adolescents
The Pyzchiva pre-filled pen is not recommended for use in children and adolescents under 18 years of age with psoriasis or Crohn's disease because it has not been studied in this age group. The pre-filled syringe should be used instead for children 6 years of age and older and adolescents with psoriasis. The solution for infusion, pre-filled syringe should be used instead for children weighing at least 40 kg with Crohn's disease.

Pyzchiva is not recommended for use in children and adolescents under 18 years of age with psoriatic arthritis, or ulcerative colitis or children with Crohn's disease who weigh less than 40 kg because it has not been studied in this age group.

Other medicines, vaccines and Pyzchiva
Tell your doctor or pharmacist:
- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Pyzchiva.
- If you received Pyzchiva while pregnant, tell your baby's doctor about your Pyzchiva treatment before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis). Live vaccines are not recommended for your baby in the first twelve months after birth if you received Pyzchiva during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- A higher risk of birth defects has not been seen in babies exposed to ustekinumab in the womb. However, there is limited experience with ustekinumab in pregnant women. It is therefore preferable to avoid the use of ustekinumab in pregnancy.
- If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Pyzchiva and for at least 15 weeks after the last Pyzchiva treatment.
- Pyzchiva can pass across the placenta to the unborn baby. If you received Pyzchiva during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals if you received Pyzchiva during your pregnancy before the baby receives any vaccine. Live vaccines such as the BCG vaccine (used to prevent tuberculosis) are not recommended for your baby in the first twelve months after birth if you received Pyzchiva during the pregnancy unless your baby's doctor recommends otherwise.
- Ustekinumab may pass into breast milk in very small amounts. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you should breast-feed or use Pyzchiva -do not do both.

Driving and using machines
Pyzchiva has no or negligible influence on the ability to drive and use machines.

Pyzchiva contains polysorbate 80 (E433)

This medicine contains 0.04 mg of polysorbate 80 (E433) in each pre-filled pen (1 ml) which is equivalent to 0.04 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Pyzchiva

Pyzchiva is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Pyzchiva is intended.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

How much Pyzchiva is given
Your doctor will decide how much Pyzchiva you need to use and for how long.

Adults aged 18 years or older
Psoriasis or Psoriatic Arthritis
- The recommended starting dose is 45 mg Pyzchiva. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or Ulcerative Colitis
- During treatment, the first dose of approximately 6 mg/kg Pyzchiva will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg Pyzchiva after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg Pyzchiva may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

How Pyzchiva is given
- Pyzchiva is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject Pyzchiva.
- However, you and your doctor may decide that you may inject Pyzchiva yourself. In this case you will get training on how to inject Pyzchiva yourself.
- For instructions on how to inject Pyzchiva, see 'Instructions for administration' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more Pyzchiva than you should
If you have used or been given too much Pyzchiva, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use Pyzchiva
If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using Pyzchiva
It is not dangerous to stop using Pyzchiva. However, if you stop, your symptoms may come

back. If you have any further questions on the use of this medicine, ask your doctor or

pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Some patients may have serious side effects that may need urgent treatment.

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs.
- Serious allergic reactions ('anaphylaxis') are rare in people taking Pyzchiva (may affect up to 1 in 1,000 people). Signs include:
  - difficulty breathing or swallowing
  - low blood pressure, which can cause dizziness or light-headedness
  - swelling of the face, lips, mouth or throat.
- Common signs of an allergic reaction include skin rash and hives (these may affect up to 1 in 100 people).

In rare cases, allergic lung reactions and lung inflammation have been reported in patients who receive ustekinumab. Tell your doctor right away if you develop symptoms such as cough, shortness of breath, and fever.

If you have a serious allergic reaction, your doctor may decide that you should not use Pyzchiva again.

Infections – these may need urgent treatment. Tell your doctor straight away if you notice any of the following signs.
- Infections of the nose or throat and common cold are common (may affect up to 1 in 10 people)
- Infections of the chest are uncommon (may affect up to 1 in 100 people)
- Inflammation of tissue under the skin ('cellulitis') is uncommon (may affect up to 1 in 100 people)
- Shingles (a type of painful rash with blisters) are uncommon (may affect up to 1 in 100 people)

Pyzchiva may make you less able to fight infections. Some infections could become serious and may include infections caused by viruses, fungi, bacteria (including tuberculosis), or parasites, including infections that mainly occur in people with a weakened immune system (opportunistic infections). Opportunistic infections of the brain (encephalitis, meningitis), lungs, and eye have been reported in patients receiving treatment with ustekinumab.

You must look out for signs of infection while you are using Pyzchiva. These include:
- fever, flu-like symptoms, night sweats, weight loss
- feeling tired or short of breath; cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning when passing water
- diarrhoea
- visual disturbance or vision loss
- headache, neck stiffness, light sensitivity, nausea or confusion.

Tell your doctor straight away if you notice any of these signs of infection. These may be signs of infections such as chest infections, or skin infections or shingles or opportunistic infections that could have serious complications. Tell your doctor if you have any kind of infection that will not go away or keeps coming back. Your doctor may decide that you should not use Pyzchiva until the infection goes away. Also tell your doctor if you have any open cuts or sores as they might get infected.

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 tell your doctor straight away if you notice any of these signs.

Other side effects

Common side effects (may affect up to 1 in 10 people)**:**

- Diarrhoea
- Nausea
- Vomiting
- Feeling tired
- Feeling dizzy
- Headache
- Itching (‘pruritus’)
- Back, muscle or joint pain
- Sore throat
- Redness and pain where the injection is given
- Sinus infection

Uncommon side effects (may affect up to 1 in 100 people)**:**
- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked or stuffy nose
- Bleeding, bruising, hardness, swelling and itching where the injection is given
- Feeling weak
- Drooping eyelid and sagging muscles on one side of the face (‘facial palsy’ or ‘Bell’s palsy’), which is usually temporary
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1,000 people)**:**
- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10,000 people)**:**
- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid).
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcardor search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pyzchiva

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2 °C–8 °C). Do not freeze.
- Keep the pre-filled pen in the outer carton in order to protect from light.
- 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 in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator in the space provided on the outer carton. At any time before the end of this period, the product can be put back in the refrigerator once and kept there until the expiry date. Discard the pen if not used after the maximum period of 35 days at room temperature storage or by the original expiry date,

whichever is earlier.
- Do not shake Pyzchiva pre-filled pen. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:
- After the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see section 6 'What Pyzchiva looks like and contents of the pack').
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.

Pyzchiva is for single use only. Any unused product remaining in the syringe or pre-filled pen should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pyzchiva contains
- The active substance is ustekinumab. Each pre-filled pen contains 90 mg ustekinumab in 1 mL.
- The other ingredients are Histidine, Histidine hydrochloride monohydrate, Polysorbate 80, Sucrose, Water for injections.

What Pyzchiva looks like and contents of the pack
Pyzchiva is a clear, colourless to light yellow solution for injection. The solution may contain a few small translucent or white particles of protein. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled pen. Each pre-filled pen contains 90 mg ustekinumab in 1 mL of solution for injection.

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INSTRUCTIONS FOR USE
Pyzchiva
(ustekinumab)
injection, for subcutaneous use
Pre-filled pen

Instructions for injecting Pyzchiva using a 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:

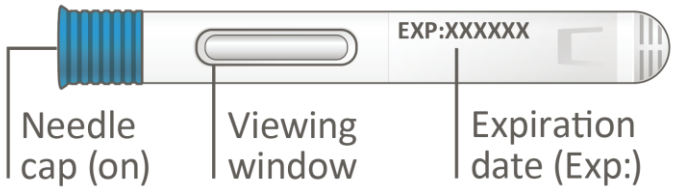
- ask your healthcare professional to help you, or
- ask someone who has been trained by a healthcare professional to give your injections.

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

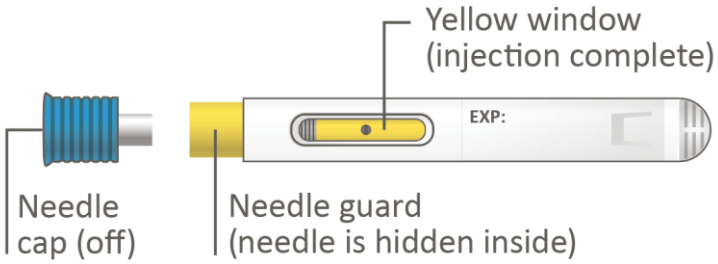


Figure A

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 in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator in the space provided on the outer carton. At any time before the end of this

period the product can be put back in the refrigerator once and kept there until the expiry date. Discard the pen if not used after the maximum period of 35 days at room temperature storage 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.")**

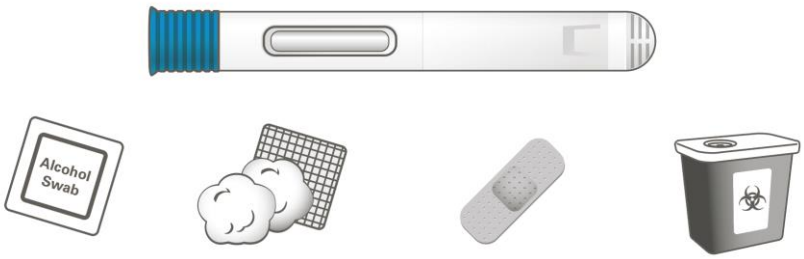


Figure B

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 window for any particles or discoloration. The medicine should look clear and colorless to light yellow with few white particles.
- **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 ºC for longer than a maximum single period of 35 days or if the pre-filled pen has been stored above 30 ºC.
  - 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.

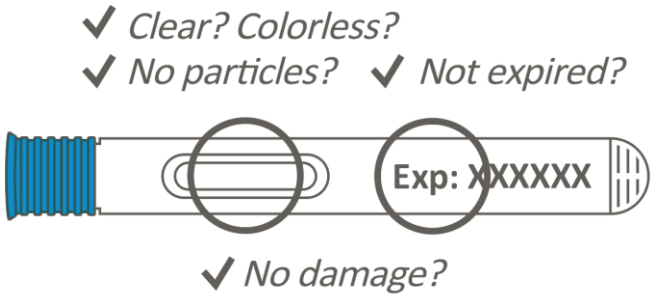


Figure C

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).**

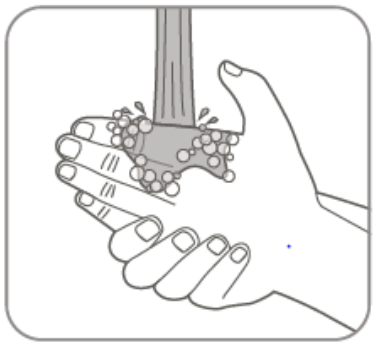


Figure D

Step 6. Choose the injection site

- Choose an injection site around your upper legs (thighs) or lower stomach area (lower abdomen) except for a 5-centimetre area right around your navel (belly-button). 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.

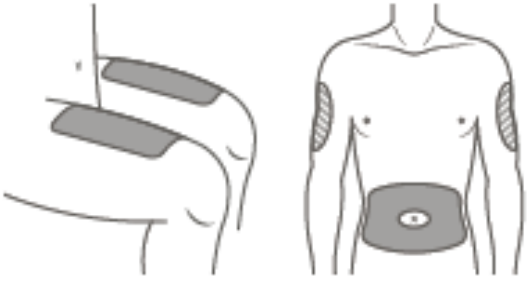


Figure E

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.

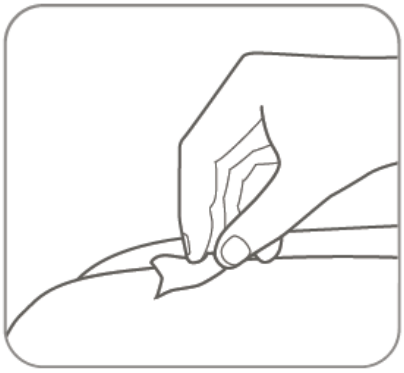


Figure F

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.

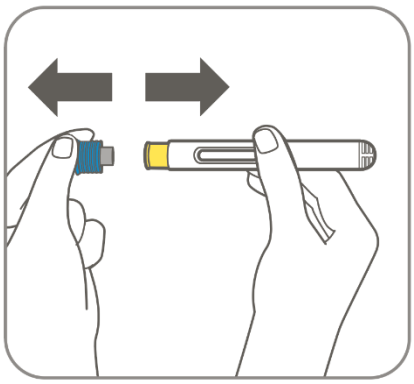


Figure G

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

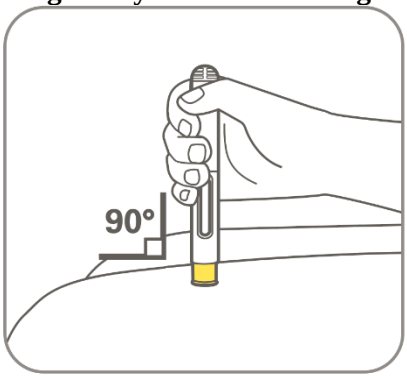


Figure H

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.

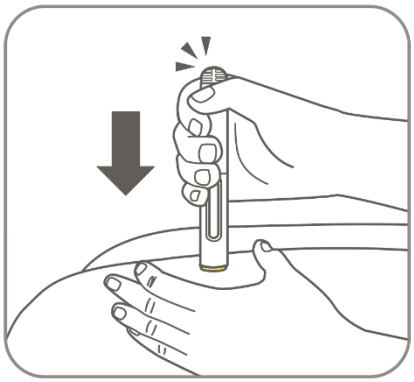


Figure I

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.

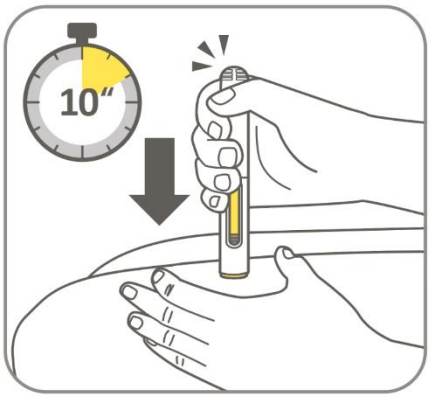


Figure J

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.

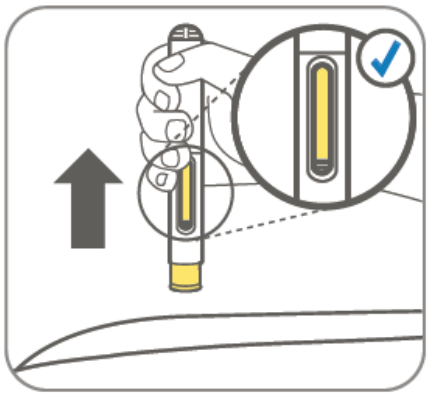


Figure K

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.