Package leaflet: Information for the user

Uzpruvo® 90 mg solution for injection in pre-filled syringe
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. If you are the parent or caregiver who will give Uzpruvo® to a child, please read this information carefully.

- 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 Uzpruvo® is and what it is used for

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

Uzpruvo® belongs to a group of medicines called 'immunosuppressants'. These medicines work by weakening part of the immune system.

What Uzpruvo® is used for
Uzpruvo® is used to treat the following inflammatory diseases:
- Plaque psoriasis - in adults and children aged 6 years and older
- 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. Uzpruvo® will reduce the inflammation and other signs of the disease.

Uzpruvo® is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

Uzpruvo® is used in children and adolescents aged 6 years and older with moderate to severe plaque psoriasis who are unable to tolerate phototherapy or other systemic therapies 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 Uzpruvo® 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 Uzpruvo® 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 Uzpruvo® to reduce the signs and symptoms of your disease.

2. What you need to know before you use Uzpruvo®

Do not use Uzpruvo®
- **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 Uzpruvo®.

Warnings and precautions
Talk to your doctor or pharmacist before using Uzpruvo®. 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 Uzpruvo®. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

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

Before you use Uzpruvo® tell your doctor
- **If you ever had an allergic reaction to Uzpruvo®**. Ask your doctor if you are not sure.
- **If you have ever had any type of cancer** – this is because immunosuppressants like Uzpruvo® 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.
- I**f 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 Uzpruvo® 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 Uzpruvo® 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 Uzpruvo®.

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 ustekinumab. 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
Uzpruvo® is not recommended for use in children with psoriasis under 6 years of age, or for use in children and adolescents under 18 years of age with psoriatic arthritis, Crohn's disease or ulcerative colitis, because it has not been studied in this age group.

Other medicines, vaccines and Uzpruvo®
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 Uzpruvo®.
- If you received Uzpruvo® while pregnant, tell your baby's doctor about your Uzpruvo® 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 six months after birth if you received Uzpruvo® during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding
- It is preferable to avoid the use of Uzpruvo® in pregnancy. The effects of Uzpruvo® in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Uzpruvo® and for at least 15 weeks after the last Uzpruvo® treatment.
- Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- Uzpruvo® can pass across the placenta to the unborn baby. If you received Uzpruvo® 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 Uzpruvo® 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 six months after birth if you received Uzpruvo® 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 Uzpruvo® - do not do both.

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

Uzpruvo® contains polysorbate 80
This medicine contains 0.04 mg of polysorbate 80 in each mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Uzpruvo®

Uzpruvo® is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Uzpruvo® 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 Uzpruvo® is given
Your doctor will decide how much Uzpruvo® 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 Uzpruvo®. 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
- **Uzpruvo® is not available for the first dose through a drip in a vein in your arm (intravenous infusion).**
- **Another ustekinumab product will be given as intravenous infusion as first dose.**
- Uzpruvo® is administered by injection under the skin (subcutaneously). You will receive the first dose of 90 mg Uzpruvo® 8 weeks after the intravenous infusion, then every 12 weeks thereafter subcutaneously. In some patients, after the first injection under the skin, 90 mg Uzpruvo® may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

Children and adolescents aged 6 years or older
Psoriasis
- The doctor will work out the right dose for you, including the amount (volume) of Uzpruvo® to be injected to give the right dose. The right dose for you will depend on your body weight at the time each dose is given.
- If you weigh less than 60 kg, there is no dosage form for Uzpruvo® for children below 60 kg body weight.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg Uzpruvo®. If you weigh more than 100 kg, the recommended dose is 90 mg Uzpruvo®.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

How Uzpruvo® is given
- Uzpruvo® is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject Uzpruvo®.
- However, you and your doctor may decide that you may inject Uzpruvo® yourself. In this case you will get training on how to inject Uzpruvo® yourself.
- For instructions on how to inject Uzpruvo®, 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 Uzpruvo® than you should
If you have used or been given too much Uzpruvo®, 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 Uzpruvo®
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 Uzpruvo®
It is not dangerous to stop using Uzpruvo®. 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 ustekinumab (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 (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 Uzpruvo® 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)

Uzpruvo® 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 Uzpruvo®. 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 disturbances 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, skin infections, 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 Uzpruvo® 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 (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 (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 (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 (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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or 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 Uzpruvo®

- 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 syringe in the outer carton in order to protect from light.
- The pre-filled syringe should be allowed to reach room temperature (approximately half an hour).
- If needed, individual Uzpruvo® pre-filled syringes may also be stored at room temperature up to 30 °C for a maximum single period of up to 30 days in the original carton in order to protect from light. Once removed from the refrigerator, record the discard date in the space provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature (up to 30 °C), it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake the pre-filled syringes. 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 Uzpruvo® 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.

Uzpruvo® is for single use only. Any unused product remaining in the syringe 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 Uzpruvo® contains
- The active substance is ustekinumab. Each pre-filled syringe contains 90 mg ustekinumab in 1 mL.
- The other ingredients are histidine, histidine monohydrochloride, polysorbate 80, sucrose, water for injections.

What Uzpruvo® looks like and contents of the pack
Uzpruvo® is a clear, colourless to slightly yellow and practically free of visible particles solution for injection. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled syringe. Each pre-filled syringe contains 90 mg ustekinumab in 1 mL solution for injection.

Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
Alvotech Hf, Sæmundargata 15-19, Reykjavik, 102, Iceland

This leaflet was last revised in August 2024.

Instructions for administration

INSTRUCTION FOR USE

Uzpruvo® 90 mg solution for injection pre-filled syringe ustekinumab for subcutaneous use

Read carefully these instructions for use before using Uzpruvo® solution for injection in pre-filled syringe.

At the start of treatment, your healthcare provider will assist you with your first injection. However, you and your doctor may decide that you may inject Uzpruvo® yourself. If this happens, you will get training on how to inject Uzpruvo®. Talk to your doctor if you have any questions about giving yourself an injection.

Important information you need to know before injecting Uzpruvo® solution for injection in pre-filled syringe

Uzpruvo® solution for injection in pre-filled syringe is not suitable for intravenous use, other ustekinumab products must be used for the initiation of treatment of Crohn's disease and ulcerative colitis.

Uzpruvo® solution for injection in pre-filled syringe is not suitable for paediatric patients below 60 kg of body weight, other ustekinumab products allowing weight-based dosing must be used.

Important information:
- For subcutaneous use only
- Do not mix Uzpruvo® with other liquids for injection
- Do not shake Uzpruvo® pre-filled syringes. This is because shaking may damage the medicine. Do not use the medicine if it has been shaken. Get a new pre-filled syringe

Check the pre-filled syringe(s) to make sure:
- the number of pre-filled syringes and strength is correct
  - If your dose is 90 mg, you will get one 90 mg pre-filled syringe of Uzpruvo®
- it is the right medicine
- it has not passed its expiry date
- the pre-filled syringe is not damaged
- the solution in the pre-filled syringe is clear and colourless to slightly yellow and practically free of visible particles
- the solution in the pre-filled syringe is not frozen
- it should be allowed to reach room temperature (approximately half an hour).

Figure 1 shows what the Uzpruvo® pre-filled syringe looks like

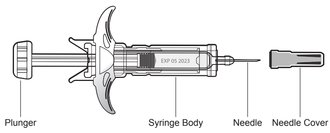


Figure 1

1. Prepare the materials
Gather the supplies you will need to prepare and to give your injection. You will need:
- Antiseptic wipes
- Cotton balls or gauze pads
- Adhesive bandage
- Your prescribed dose of Uzpruvo® (see Figure 1)
- Puncture-resistant sharps disposal container (not included). See Figure 2

Get everything together that you need and lay out on a clean surface.

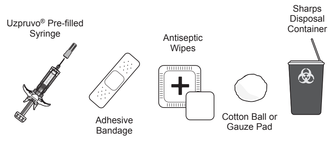
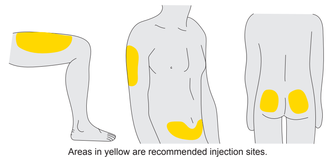


Figure 2

2. Choose and prepare the injection site:
Choose an injection site (see Figure 3)
- Uzpruvo® is given by injection under the skin (subcutaneously)
- Choose an injection site. Good places for the injection are the upper thigh (legs), buttocks, or around the belly (abdomen) at least 5 cm away from the navel (belly button)
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used (see Figure 3)
- 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



Areas in yellow are recommended injection sites.

Figure 3

Prepare the injection site
- Wash your hands very well with soap and warm water
- Clean the skin with the antiseptic wipe where you plan to give your injection
- Do not touch this area again before giving the injection. Let your skin dry before injection
- Do not fan or blow on the clean area
- Do not inject through clothes

3. Remove the needle cover (see Figure 4):
- Remove the needle cover when you are ready to inject Uzpruvo®
- Do not touch the plunger while removing the needle cover
- Hold the body of the pre-filled syringe with one hand, and pull the needle cover straight off (see Figure 4)
- Put the needle cover in the trash. Do not recap
- You may also see a drop of liquid at the end of the needle. This is normal
- Do not touch the needle or let it touch anything
- Inject the dose promptly after removing the needle cover

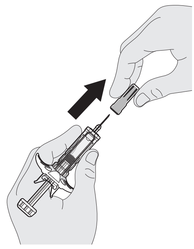


Figure 4

4. Inject the dose:
Grasp the syringe:
- Hold the body of the pre-filled syringe with one hand between the thumb and index finger (see Figure 5)
- Do not use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist for instructions
- Do not pull back on the plunger at any time

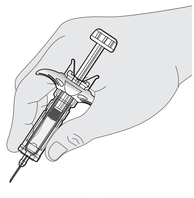


Figure 5

Pinch the skin and insert needle:
- Use the other hand to gently pinch the cleaned area of the skin. Hold firmly
- Use a quick, dart-like motion to insert the needle into the pinched skin at about 45-degree angle (see Figure 6)

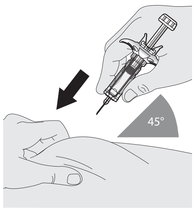


Figure 6

Inject the drug:
- Inject all of the liquid by using your thumb to push in the plunger all the way in until the pre-filled syringe is empty (see Figure 7)

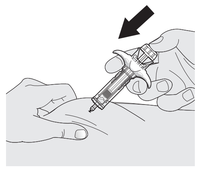


Figure 7

Allow the needle to retract:
- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin
- Slowly take your thumb off the plunger head. The plunger will move up with your finger and retract the needle into the needle guard (see Figure 8)

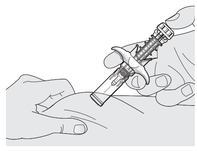


Figure 8

5. After the injection:
- After completing the injection, press a cotton ball or gauze pad on the skin of the injection site for a few seconds after the injection (see Figure 9)
- There may be a slight bleeding at the injection site. This is normal
- Do not rub the skin at the injection site
- You may cover the injection site with a small adhesive bandage, if necessary

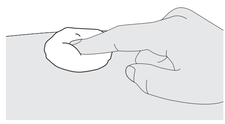


Figure 9

6. Disposal:
- Put the used syringes in a puncture-resistant container, like a sharps disposal container right away after use according to your local regulations. Do not throw away (dispose of) loose syringes in your household garbage (see Figure 10).
- Dispose of the antiseptic wipes, cotton ball or gauze pad, and packaging in your garbage
- Never re-use a syringe, for your safety and health, and for the safety of others

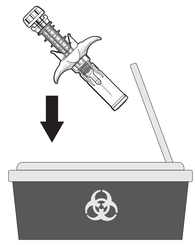


Figure 10

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