

EPYZTEK[®] INJECTION

Ustekinumab (rmc)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Epyztek (pronounced ep-eez-tek). It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Epyztek against the benefits this medicine is expected to have for you.

If you have any concerns about using Epyztek, ask your doctor or pharmacist.

It is important that you read this leaflet.

Keep this leaflet with your medicine. You may need to read it again.

What Epyztek is used for

Epyztek is a prescription medicine that is used to treat:

- adults with moderate to severe plaque psoriasis that is chronic (doesn't go away),
- adults with active psoriatic arthritis, an inflammatory disease of the joints that is usually accompanied by psoriasis,
- adults with moderately to severely active Crohn's disease, an inflammatory disease of the bowel.

Epyztek contains the active ingredient ustekinumab, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind to other unique proteins.

Ustekinumab blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). IL-12 and IL-23 are made by your body's

immune system. In people with psoriasis, psoriatic arthritis, Crohn's disease, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body like the skin and nails.

Ustekinumab can block IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use Epyztek

When you must not use it

Do not use Epyztek if you have an allergy to:

- ustekinumab, the active ingredient in the medicine
- any of the other ingredients in Epyztek. See Product Description at the end of this leaflet for a list of ingredients.

Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not use Epyztek if the packaging is torn or shows signs of tampering, or if the liquid is discoloured or cloudy.

Do not use Epyztek beyond the expiry date (month and year) printed on the pack.

Do not use Epyztek if you know or think that it may have been exposed to extreme temperatures (such as

being accidentally frozen or heated).

Before you start to use it

You must tell your doctor about all of your medical conditions before each treatment, including if you:

- 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 had TB (tuberculosis), 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 lesions within psoriasis areas or on normal skin
- have recently received or are scheduled to receive a vaccine. Patients receiving Epyztek should not receive live vaccines. Tell your doctor 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 allergy immunotherapy
- are pregnant, planning to become pregnant, or breastfeeding. Adequate contraception should be used to avoid falling pregnant. Epyztek should only be used during a pregnancy if needed. Epyztek may pass into your breastmilk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use Epyztek as it might be excreted in breast milk

Your doctor will examine you for tuberculosis (TB). If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Epyztek and during treatment with Epyztek.

If you have not told your doctor or

pharmacist about any of the above, tell them before you start using or are given Epyztek.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

You should not receive a live vaccine while taking Epyztek. If you used Epyztek while pregnant, tell your baby's doctor about your Epyztek use before the baby receives any vaccines, including live vaccines, such as the BCG vaccines (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.

Using Epyztek

For the treatment of psoriasis or psoriatic arthritis Epyztek is given by injection just under the skin (subcutaneously).

For the treatment of Crohn's Disease, the first dose of Epyztek will be given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. After this starting dose, all future doses of Epyztek are given by injection just under the skin (subcutaneously).

All Epyztek injections are for single use in one patient only.

Epyztek is intended for use under the guidance and supervision of your doctor. When you start treatment, Epyztek may be injected by your healthcare provider. If your doctor determines that it is appropriate, you or your caregiver may be able to administer it under the skin yourself if you wish, after proper training in injection technique. (See How much to use and Injecting Epyztek under the skin yourself).

It is important to remember that the first dose of Epyztek for the treatment of Crohn's Disease (intravenous infusion) will always be administered by your healthcare provider.

How much to use

- Your doctor will determine the correct dose of Epyztek for you and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

Injecting Epyztek under the skin yourself

Your healthcare provider may decide that it is right for you or your caregiver to learn how to inject Epyztek under the skin (subcutaneously) yourself. If you would like to self-inject Epyztek under your skin, you or your caregiver must be trained by a healthcare professional to prepare an injection and give it to yourself. If you 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.

Epyztek is given alone and not mixed with other liquids for injection.

Epyztek should not be used:

- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discoloured, cloudy or you can see other particulate matter floating in it;
- if you know, or think that it may have been exposed to extreme temperatures (such as being accidentally frozen or heated).

Do not shake Epyztek at any time.

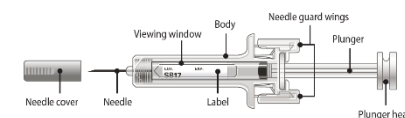
Prolonged vigorous shaking may damage the product. If Epyztek has been shaken vigorously, don't use it. Epyztek is not to be mixed with other liquids for injection.

How to inject Epyztek from a pre-filled syringe

To reduce the risk of accidental needle stick injuries 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.

1. PREPARING FOR PRE-FILLED SYRINGE USE



Take the syringe(s) out of the refrigerator.

Make sure that it is the right dose. If your dose is 45 mg, you will receive one 45 mg syringe. If your dose is 90 mg, you may receive two 45 mg syringes. If you receive two 45 mg syringes for a 90 mg dose, you will need to give yourself two injections one right after the other. Check with your healthcare provider.

Check Expiration Date

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

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 not cloudy and not frozen.

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.

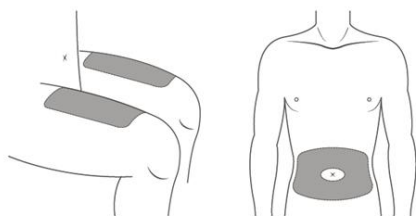
DO NOT remove the needle cover from the pre-filled syringe.

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



*Areas in gray are recommended injection sites.

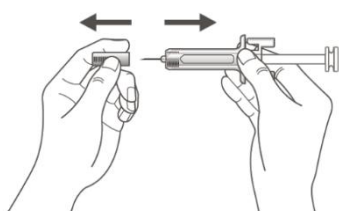
and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.

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 with one hand and pull the needle cover straight off.

Throw the needle cover into the rubbish.

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 the 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.

4. INJECT THE MEDICATION

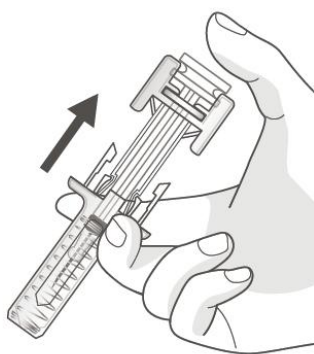
Gently pinch the cleaned

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 gently 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.



5. 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. See 'After using Epyztek - Disposal'.

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.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

If you forget to use it

- Make the next injection as soon as you remember, and then continue to use it as you would normally.
- Do not administer a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you have used too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- New Zealand: 0800 POISON or 0800 764 766
- Australia: 13 11 26

Keep these telephone numbers handy.

While you are using Epyztek

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor about your medical conditions before each treatment (see Before you use Epyztek).
- Tell your doctor if you become pregnant while using Epyztek.
- If you used Epyztek while pregnant, tell your baby's doctor

about your Epyztek use before the baby receives any vaccines, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.

- If you develop headache, vision problems, seizures or change in mental status (for example confusion), tell your doctor immediately.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Epyztek.

Things you must not do

- You should not receive a live vaccine while taking Epyztek.
- Do not use Epyztek to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Epyztek.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you

experience any of the following common side effects:

- Upper respiratory infections such as sinus infection and colds
- Dizziness, headache
- Sore throat
- Diarrhoea
- Nausea, vomiting
- Pruritus (itching)
- Back or muscle pain
- Joint pain
- Injection site pain or redness
- Fatigue (tiredness)
- Sinus infection

Other uncommonly reported side effects include:

- Painful skin rash (Herpes Zoster infection) or blister
- Cellulitis
- Dental infections
- Viral upper respiratory tract infection
- Vaginal yeast (fungal) infection
- Depression
- Blocked or stuffy nose
- Acne
- Injection site reactions (including bleeding, bruising, hardness, swelling and itch)
- Feeling weak
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Worsening reddening or shedding/peeling of the skin

Tell your doctor immediately or go to hospital as you need urgent medical attention:

- A serious allergic reaction. Signs of a serious allergic reaction may include a skin rash, a swollen face, lips, mouth or throat, or wheezing, dizziness, trouble swallowing or breathing.

Epyztek is a medicine that may decrease the activity of your immune system. It can increase your chances of getting serious side

effects. Tell your doctor immediately if you notice any of the following, as you may need urgent medical care:

- Serious Infections. Epyztek may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection, tell your healthcare provider before you start using Epyztek. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or have any open cuts or sores, tell your healthcare provider right away.
- Cancer. Many drugs such as Epyztek that may decrease the activity of the immune system may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other side effects, particularly if they bother you or do not go away.

After using Epyztek

Storage

Store Epyztek between 2°C and 8°C in the refrigerator. Do not freeze. Keep the product in the original carton to protect from light until the time of use. Do not shake.

Keep your medicines out of reach of children.

Do not store Epyztek, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy some medicines.

If needed, you may store Epyztek pre-filled syringes at room temperature up to 30°C for one period of up to 1 month.

- Write the date on the carton, when removed from the refrigerator.
- Anytime before the end of this period the product can be put back in the refrigerator

- Throw away pre-filled syringe if it has been kept for 1 month at room temperature storage and has not been used or reached its original expiry.

Disposal

After injection, used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your state or local regulations. Antiseptic wipes and other supplies can be placed in regular rubbish.

If your doctor tells you to stop using Epyztek, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that may be left over.

Each mL of Epyztek contains 5 mg of ustekinumab.

Inactive ingredients: Histidine, histidine hydrochloride monohydrate, sucrose, polysorbate 80, methionine, disodium edetate, and water for injections.

No preservatives are present.

Sponsor

SAMSUNG BIOEPIS NZ LTD

TMF Group, Level 11, 41 Shortland Street

Auckland 1010

New Zealand

Telephone:

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Product Description

What it looks like

Epyztek injection for subcutaneous use is a colourless to light yellow solution.

Epyztek solution for intravenous use is a clear, colourless to light yellow product.

Epyztek for subcutaneous use is available in pre-filled syringes containing 45 mg ustekinumab in 0.5 mL or 90 mg ustekinumab in 1.0 mL. Each box contains 1 syringe.

Epyztek for intravenous use is available in glass vials containing 130 mg ustekinumab in 26 mL.

Ingredients

Epyztek 45 mg or 90 mg solution for injection for subcutaneous administration

Each pre-filled syringe contains 45mg or 90 mg of ustekinumab.

Inactive ingredients: Histidine, histidine hydrochloride monohydrate, sucrose, polysorbate 80, and water for injections.

No preservatives are present.

Epyztek 130 mg concentrate for solution for intravenous infusion