

Package leaflet: Information for the patient

Kyntheum 210 mg solution for injection in pre-filled syringe brodalumab

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Kyntheum is and what it is used for

Kyntheum contains the active substance brodalumab. Brodalumab is a monoclonal antibody, a specialised type of protein that recognises and attaches to certain proteins in the body.

Brodalumab belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by blocking the activity of IL-17 proteins, which are present at increased levels in diseases such as psoriasis.

Kyntheum is used to treat a skin condition called “plaque psoriasis”, which causes inflammation and scaly plaque formation on the skin. Kyntheum is used in adults with moderate to severe plaque psoriasis affecting large areas of the body.

Using Kyntheum will benefit you by leading to improvements of skin clearance and reducing psoriasis signs and symptoms, such as itch, redness, scaling, burning, stinging, cracking, flaking and pain.

2. What you need to know before you use Kyntheum

Do not use Kyntheum:

- if you are allergic to brodalumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Kyntheum
- if you have active Crohn’s disease
- if you have an infection which your doctor thinks is important (for example, active tuberculosis).

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before using Kyntheum:

- if you have an inflammatory disease affecting the gut named Crohn's disease
- if you have an inflammation of the large intestine named ulcerative colitis
- if you have ever had or are having suicidal thoughts or actions, depression, anxiety, or mood problems
- if you have an infection now or often get infections
- if you have a long-term (chronic) infection
- if you have tuberculosis (TB), have had a positive TB test, or have been in close contact with someone with TB. You may be treated with another medicine for TB before you begin treatment with Kyntheum
- if you have recently received or are scheduled to receive a vaccination. You should not be given certain types of vaccines (called 'live vaccines') while being treated with Kyntheum
- if you have used Kyntheum during the last three months of your pregnancy, you should talk to your doctor before vaccinating your baby
- if you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

After starting Kyntheum, tell your doctor, pharmacist or nurse immediately:

- if you have been told by your doctor that you have developed Crohn's disease
- if you feel depressed, anxious, or have thoughts of suicide, or have unusual mood changes
- if you have an infection or have any signs of infection listed in Section 4 "Possible Side Effects"
- if you have been told you have tuberculosis.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using Kyntheum and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (any signs of bowel problems).

Look out for allergic reactions

Kyntheum can potentially cause serious side effects, including allergic reactions. You must look out for signs of these conditions while you are taking Kyntheum.

Stop using Kyntheum and tell your doctor or seek medical help immediately if you notice any signs indicating an allergic reaction. Such signs are listed under "Serious side effects" in section 4.

Children and adolescents

Kyntheum is not recommended for children and adolescents (below 18 years of age) because it has not been studied in this age group.

Other medicines and Kyntheum

Tell your doctor or pharmacist:

- if you are taking, have recently taken or might take any other medicines
- if you have recently had or you or your baby are going to have a vaccination, see "Warnings and precautions" in section 2. "What you need to know before using Kyntheum".

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Kyntheum has not been tested in pregnant women and it is not known if this medicine can harm your unborn baby. It is therefore preferable to avoid the use of Kyntheum during pregnancy. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and should use adequate contraception while using Kyntheum and for at least 12 weeks after the last dose of Kyntheum.

It is not known whether brodalumab passes into breast milk. Tell your doctor if you are breast-feeding or plan to breast-feed. Your doctor will then help you decide whether to stop breast-feeding or stop

using Kyntheum. Together you will consider the benefit of breast-feeding to the baby and the benefit of Kyntheum to you.

Driving and using machines

Kyntheum is unlikely to affect your ability to drive and use machines.

3. How to use Kyntheum

Kyntheum should be prescribed to you by a doctor with experience in diagnosing and treating psoriasis.

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much Kyntheum is given

- Your doctor will decide how much Kyntheum you need and for how long. The recommended dose is 210 mg (one injection).
- After the first dose you will need to have a weekly injection at Week 1 (one week after the first dose) and Week 2 (two weeks after the first dose). After that, you will need to have an injection every two weeks.
- Kyntheum is for long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. Tell your doctor if you think your signs and symptoms of psoriasis are not improving after using Kyntheum.

How is Kyntheum given

Kyntheum is given as an injection under the skin (known as a subcutaneous injection).

Self-administration instructions

See the detailed “Instructions for Use” that comes with this medicine for information on the right way to store, prepare, and give your injections at home.

- If your doctor decides that you or a caregiver can give the injections at home, you or your caregiver should receive training on the right way to prepare and inject Kyntheum. Do not try to inject Kyntheum until you or your caregiver have been shown how to inject Kyntheum by your doctor or nurse.
- Do not shake the pre-filled syringe before use.
- Kyntheum is injected in your upper legs (thighs) or stomach area (abdomen) by you or a caregiver. A caregiver may also give you an injection in your upper, outer arm.
- Do not inject into an area of the skin that is tender, bruised, red, hard or in an area of skin that is affected by psoriasis.

If you use more Kyntheum than you should

If you use more of this medicine than prescribed or take the dose sooner than required, tell your doctor.

If you forget to use Kyntheum

If you have forgotten to inject a dose of Kyntheum, inject the next dose as soon as you can after the missed dose. Then, talk to your doctor about when you should inject the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Kyntheum

You should not stop using Kyntheum without speaking to your doctor first. If you stop treatment, symptoms of psoriasis may come back.

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

4. Possible side effects

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

Serious side effects

Stop using Kyntheum and tell your doctor or seek medical help immediately if you get any of the following side effects. Your doctor will decide if and when you may restart the treatment:

Serious allergic reaction (may affect up to 1 in 1,000 people), the signs may include:

- difficulty breathing or swallowing
- low blood pressure, which can cause dizziness or light-headedness
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

Possible serious infections (may affect up to 1 in 100 people), the signs may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters.

Other side effects

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

- diarrhoea
- feeling sick
- redness, pain, itching, bruising, or bleeding at injection site
- tiredness
- mouth or throat pain
- tinea (fungal) skin infections (including on feet and groin)
- flu (influenza)
- headache
- joint pain
- muscle pain.

Uncommon (may affect up to 1 in 100 people)

- candida (fungal) infection in the mouth, throat or genitals
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- low white blood cell count.

Most of these side effects are mild to moderate. If any of these side effects becomes severe, tell your doctor, nurse, or pharmacist.

Abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems) have also been reported with IL-17 inhibitors, such as Kyntheum.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Kyntheum

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and label of the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Keep the pre-filled syringe in the outer carton in order to protect from light.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Kyntheum can be kept at room temperature up to 25°C in the outer carton for 14 days. Throw away Kyntheum if it is not used within 14 days of storage at room temperature.

Do not use this medicine if you notice the solution is cloudy or discoloured or contains lumps, flakes or particles.

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 Kyntheum contains

- The active substance is brodalumab. Each pre-filled syringe contains 210 mg brodalumab in 1.5 ml solution.
- The other ingredients are proline, glutamate, polysorbate 20 and water for injections.

What Kyntheum looks like and contents of the pack

Kyntheum is a solution for injection that is a clear to slightly pearly, colourless to slightly yellow liquid, with no particles.

Kyntheum is available in unit packs containing 2 pre-filled syringes and in multipacks comprising 3 cartons, each containing 2 pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Industriparken 55
DK-2750 Ballerup
Denmark

Manufacturers

Laboratoires LEO
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28500 Vernouillet
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This leaflet was last revised in March 2022.

For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333.

**Instructions for Use:
Kyntheum® 210 mg
solution for injection in pre-filled syringe
brodalumab**

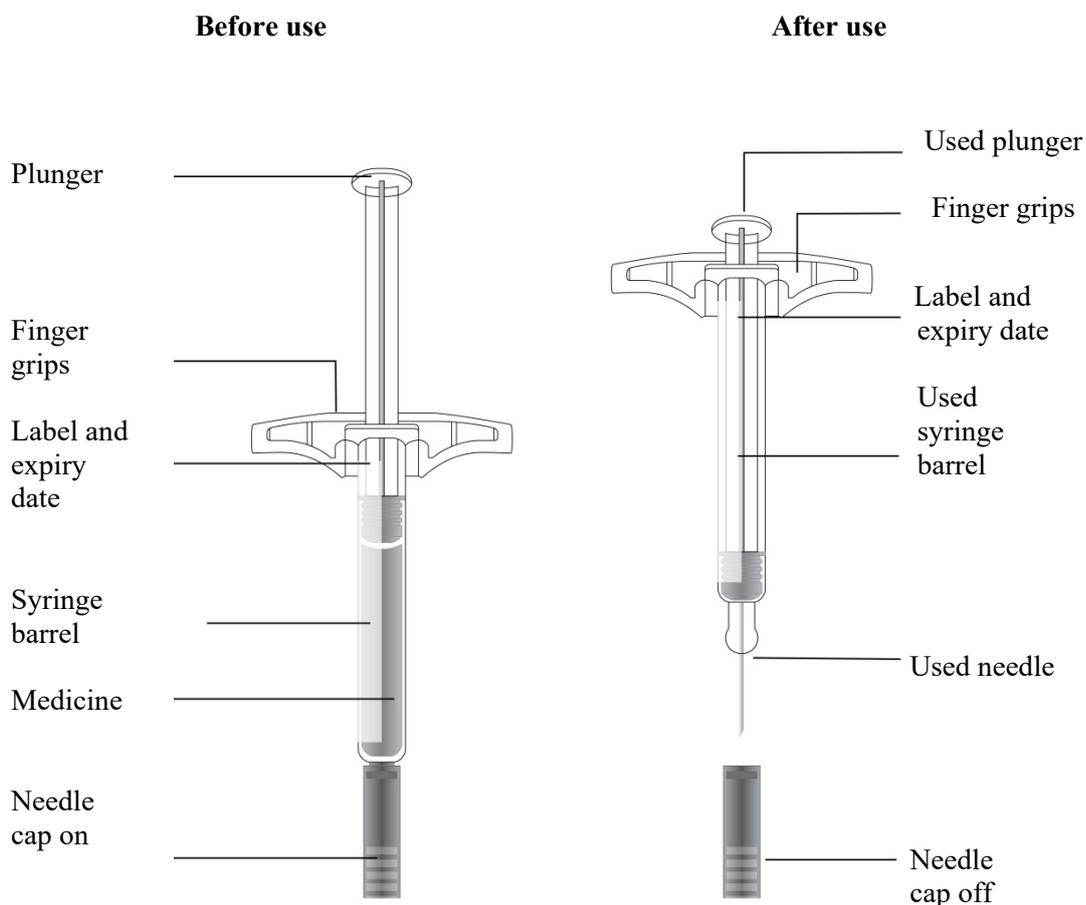
For subcutaneous use

Kyntheum is available as a single-use pre-filled syringe. Each syringe contains one 210 mg dose of Kyntheum. Your doctor, pharmacist or nurse will tell you how often to inject the medicine. **Each Kyntheum pre-filled syringe can only be used once.**

If your doctor decides that you or a caregiver can give you injections at home, you should receive training on the right way to prepare and inject Kyntheum. Do not try to inject yourself until your healthcare provider has shown you the right way to give the injections.

Please read all the instructions before using the Kyntheum pre-filled syringe. Call your doctor, pharmacist or nurse if you or your caregiver have any questions about the right way to inject Kyntheum.

Guide to parts



Important: Needle is inside

Before you use a Kyntheum pre-filled syringe, read this important information:

Storing your Kyntheum pre-filled syringes

- Keep out of the sight and the reach of children.

- Keep the pre-filled syringe in the original carton in order to protect from light or physical damage.
- Keep in the refrigerator (2°C to 8°C).
- If needed, you may store the Kyntheum pre-filled syringe at room temperature up to 25°C for up to 14 days. Throw away Kyntheum that has been stored at room temperature for longer than 14 days.
- **Do not** freeze.

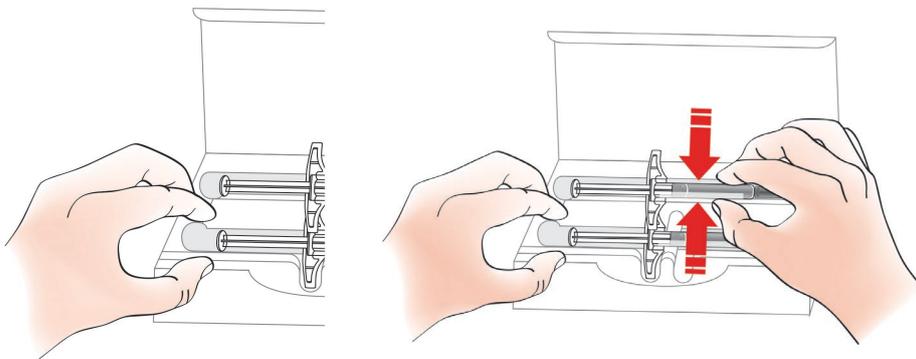
Using your Kyntheum pre-filled syringe

- **Do not** use after the expiry date on the label.
- **Do not** shake.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** use a Kyntheum pre-filled syringe if it has been dropped on a hard surface. This is in case the syringe is broken.

Step 1: Preparing

A. Remove the Kyntheum pre-filled syringe from the box

Grab the syringe barrel to remove the syringe from the tray.



Place finger or thumb on edge of tray to secure it while you remove syringe.

Grab here

Put the box with any unused syringes back in the refrigerator.

For safety reasons:

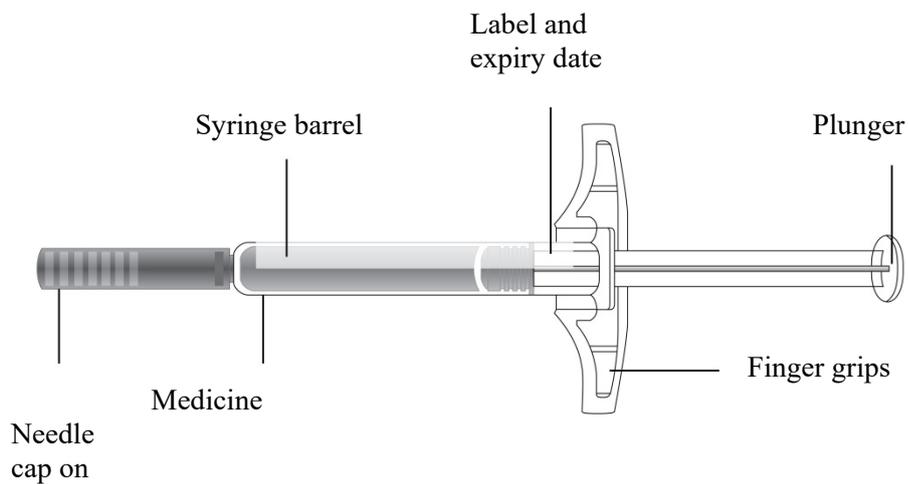
- **Do not** hold the plunger.
- **Do not** grasp the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger grips. They are part of the syringe.

Leave the syringe at room temperature for at least **30** minutes before injecting.

- **Do not** put the syringe back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the syringe by using a heat source such as hot water or a microwave.
- **Do not** leave the syringe in direct sunlight.
- **Do not** shake the syringe.

Important: Always hold the pre-filled syringe by the syringe barrel.

B. Check the Kyntheum pre-filled syringe



Make sure the medicine in the syringe is clear to slightly pearly and colourless to slightly yellow.

- **Do not** use the syringe if:
 - the medicine is cloudy or discoloured or contains flakes or particles
 - any part appears cracked or broken.

C. Collect all the materials you need

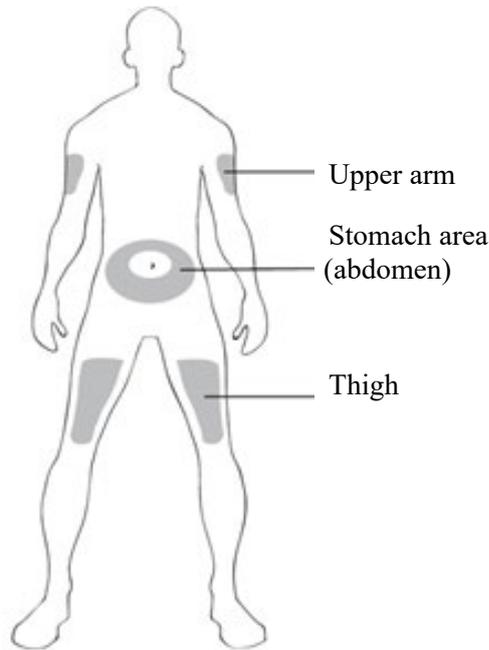
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- new syringe
- alcohol wipes
- cotton ball or gauze pad
- plaster
- sharps disposal container (colour and appearance of container may differ depending on national requirements).



D. Prepare and clean the area where you will inject



You or your caregiver can use:

- your thigh
- your stomach area (abdomen), except for a 5-centimetre area right around your belly button (navel).

Only your caregiver can use:

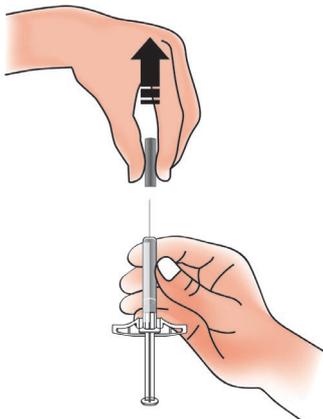
- your outer area of upper arm.

About the injection area:

- **Do not** inject into areas where the skin is tender, bruised red, or hard.
- Avoid injecting into areas with scars or stretch marks.
- Avoid injecting directly into raised, thick, red or scaly skin patches or lesions.
- Clean the area where you plan to inject with an alcohol wipe. Let your skin dry.
- **Do not** touch this area again before injecting.
- If you want to use the same injection area each time, make sure it is not exactly the same spot that you used for a previous injection.

Step 2: Getting ready to inject

E. When you are ready to inject, pull the needle cap straight out and away from your body

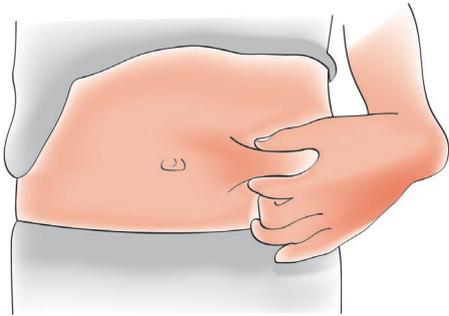


Throw the needle cap into the sharps disposal container provided.

- **Do not** twist or bend the needle cap.
- **Do not** put the needle cap back onto the syringe.

You may notice a small air bubble in the syringe or a drop of liquid at the end of the needle. Both are normal and do not need to be removed.

F. Pinch your skin to create a firm surface



Pinch the skin firmly between your thumb and fingers, creating an area about 5 centimetres wide.

Important: Keep the skin pinched until after you have injected.

Step 3: Injecting

G. Hold the pinched skin. With the needle cap off, insert the syringe into your skin at somewhere between 45 and 90 degrees

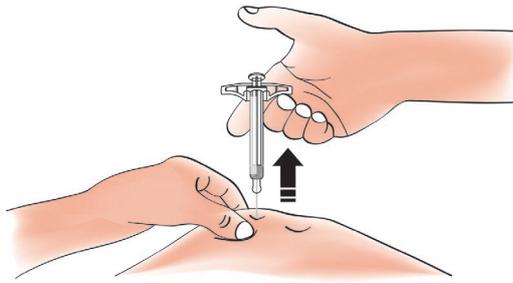


Do not place your finger on the plunger while inserting the needle.

H. Using slow and constant pressure, push the plunger all the way down until it stops moving



I. When you have finished, release your thumb. Then, gently remove the syringe from your skin



Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your doctor, pharmacist or nurse immediately.

Step 4: Finishing up

J. Throw away the used syringe



- Put your used pre-filled syringe in a puncture resistant sharps disposal container straight after use.
- **Do not** re-use the syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household rubbish.

Important: Always keep the sharps disposal container out of the sight and the reach of children.

K. Check the injection site

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Cover with plaster if needed.