Package leaflet: Information for the user

EXDENSUR 100 mg solution for injection in pre-filled syringe
depemokimab

▼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.
- 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 EXDENSUR is and what it is used for
2. What you need to know before you use EXDENSUR
3. How to use EXDENSUR
4. Possible side effects
5. How to store EXDENSUR
6. Contents of the pack and other information
7. Step-by-step instructions for use

1. What EXDENSUR is and what it is used for

EXDENSUR contains the active substance **depemokimab**, a *monoclonal antibody*, a type of protein designed to recognise and bind to a specific target substance in the body. It is used to treat asthma in adults and adolescents over 12 years of age who are on a maximum moderate-dose or high-dose inhaled corticosteroids (ICS) plus another asthma controller. EXDENSUR is also used to treat severe CRSwNP (chronic rhinosinusitis with nasal polyps) in adults.

EXDENSUR works by blocking a key protein and reducing inflammation that plays a major role in asthma and CRSwNP.

The active substance in EXDENSUR, blocks a protein called interleukin-5. By blocking the action of this protein, it limits the production of *eosinophils* (a type of white blood cell) from the bone marrow and lowers the number of *eosinophils* in the bloodstream.

Asthma
Inflammation in your lungs and airways leads to the signs and symptoms of asthma.

If your asthma is not well controlled by your existing treatment, EXDENSUR may reduce your number of asthma attacks.

Severe chronic rhinosinusitis with nasal polyps (CRSwNP)
Inflammation in your nose and sinuses can cause symptoms such as a blocked nose and loss of smell, and soft jelly-like growths (called nasal polyps) to form inside the nose. EXDENSUR helps reduce symptoms (e.g. nasal congestion, nasal discharge, loss of smell), the size of your nasal polyps and the use of oral corticosteroid medicines. EXDENSUR may help prevent surgery for your nasal polyps.

2. What you need to know before you use EXDENSUR

Do not use EXDENSUR:
- if you are **allergic** to depemokimab or any of the other ingredients of this medicine (listed in section 6).

➔ **Check with your doctor** if you think this applies to you.

Warnings and precautions
Talk to your doctor before using this medicine.

Worsening of asthma
EXDENSUR must not be used to treat sudden breathing problems that may occur with asthma.

Some people get asthma-related side effects, or their asthma may become worse, during treatment with EXDENSUR.

➔ **Tell your doctor or nurse** if your asthma remains uncontrolled, or gets worse, after you start EXDENSUR treatment.

Allergic reactions
Medicines of this type *(monoclonal antibodies)* can cause allergic reactions when injected into the body (see section 4, 'Possible side effects').

If you have had a similar reaction to any injection or medicine:

➔ **Tell your doctor before you are given EXDENSUR**

Parasitic infections
EXDENSUR may weaken your resistance to infections caused by parasites. If you have a parasitic infection, it should be treated before you start treatment with EXDENSUR. If you live in a region where these infections are common or if you are travelling to such a region:

➔ **Check with your doctor** if you think any of these may apply to you.

Keeping a record
It is important to keep a record of the batch number of your medicine. Every time you get a new pack of EXDENSUR pre-filled syringe keep a note of the batch number (which is on the packaging after Lot) and keep this information to hand when talking to your doctor or pharmacist.

Children and adolescents

This medicine is not intended for use in **children below 12 years of age** for the treatment of asthma, or in **children or adolescents below 18 years of age** for the treatment of severe CRSwNP.

Other medicines and EXDENSUR
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Other medicines for asthma or CRSwNP

- ✘ Don't suddenly stop taking your medicines for your asthma or CRSwNP once you have started EXDENSUR. These medicines (especially ones called corticosteroids) must be stopped gradually, under the direct supervision of your doctor.

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 for advice before taking this medicine.
It is not known whether the ingredients of EXDENSUR can pass into breast milk. If you are breast-feeding, you must check with your doctor before you use EXDENSUR.

Driving and using machines
EXDENSUR is unlikely to affect your ability to drive or use machines.

EXDENSUR contains polysorbates
This medicine contains 0.2 mg of polysorbate 80 per 100 mg dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

EXDENSUR contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 100 mg dose, that is to say essentially "sodium-free".

3. How to use EXDENSUR

Asthma

The recommended dose for adults and adolescents aged 12 years and over is 100 mg. You will have 1 injection every 6 months under the skin (subcutaneous).

Severe CRSwNP

The recommended dose for adults is 100 mg. You will have 1 injection every 6 months under the skin.

How to use

EXDENSUR is given by injection under the skin.

Your doctor or nurse will decide if you or your caregiver can inject EXDENSUR. They will then provide training to show you or your caregiver the correct way to use EXDENSUR.

You can inject EXDENSUR under your skin in your stomach area (abdomen) or upper leg (thigh). Your caregiver can also inject EXDENSUR into your upper arm. You must not give injections into areas where the skin is tender, bruised, red, or hard.

Call your doctor or nurse if you experience difficulties during the self-administration and have any concerns regarding an incomplete injection.

If you forget to use EXDENSUR
If your doctor or healthcare professional gives you your injection of EXDENSUR:

➔ Contact your doctor or hospital as soon as possible to re-schedule your appointment.

If you or your caregiver forget to give the injection of EXDENSUR:

➔ If you miss a dose, inject a dose of EXDENSUR as soon as possible. After that, continue EXDENSUR on your usual injection day as planned.

➔ If you miss a dose by 1 month or more, inject a dose of EXDENSUR and restart your 6-month injection schedule from the day you take the missed dose. If you are not sure what to do, ask your doctor, pharmacist or nurse.

Don't stop EXDENSUR without advice
Do not stop injections of EXDENSUR unless your doctor advises you to. Interrupting or stopping the treatment with EXDENSUR may cause your symptoms to come back.
If your symptoms get worse while receiving injections of EXDENSUR

➔ Call your doctor.

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.

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

- itching
- headache, tiredness, or rash around the time of injection
- injection site reactions (e.g. pain, redness, swelling, or itching at the site of the injection)

Uncommon side effects
(may affect **up to 1 in 100** people)

- allergic reactions

➔ Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

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 Yellow Card Scheme Website: 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 EXDENSUR

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Do not shake.

Store in the original package in order to protect from light.

The pre-filled syringe can be removed from the refrigerator and kept in its unopened carton for up to 7 days at room temperature (up to 30°C), when protected from light. After 7 days out of the refrigerator, dispose of the syringe according to local requirements.

The pre-filled syringe must be used within 8 hours once the carton is opened. Discard if not used within 8 hours.

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 EXDENSUR contains

- The active substance is depemokimab. Each mL of solution contains 100 mg of depemokimab.
- The other ingredients are histidine, histidine monohydrochloride, trehalose dihydrate, arginine hydrochloride, disodium edetate, polysorbate 80 (E 433), water for injections.

What EXDENSUR looks like and contents of the pack

EXDENSUR is supplied as a 1 mL colourless, yellow to brown, clear to opalescent solution in a single-use pre-filled syringe.

EXDENSUR is available in a pack containing 1 pre-filled syringe.

Marketing Authorisation Holder
GlaxoSmithKline UK Limited
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United Kingdom

Manufacturer
Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations)
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Barnard Castle
County Durham
DL12 8DT
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Other formats
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Exdensur**
Reference number PL 19494/0329

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in May 2026.

7. Step by step instructions for using the pre-filled syringe

EXDENSUR
(depemokimab)
injection, for subcutaneous use
100 mg

This Instructions for Use contains information on how to inject EXDENSUR.

Read These Sections First

Before using your pre-filled syringe, it is important that your healthcare provider explains your EXDENSUR dosing instructions, and shows you (or your caregiver) how to use the syringe the right way.

It is important to keep a record of the batch number of your medicine. Every time you get a new pack of EXDENSUR pre-filled syringe keep a note of the batch number (which is on the packaging after Lot) and keep this information to hand when talking to your doctor or pharmacist.

Important Information

Read all of these instructions before using your syringe. If you do not follow these instructions, you may not get all your medicine.

Do not use the EXDENSUR syringe if:

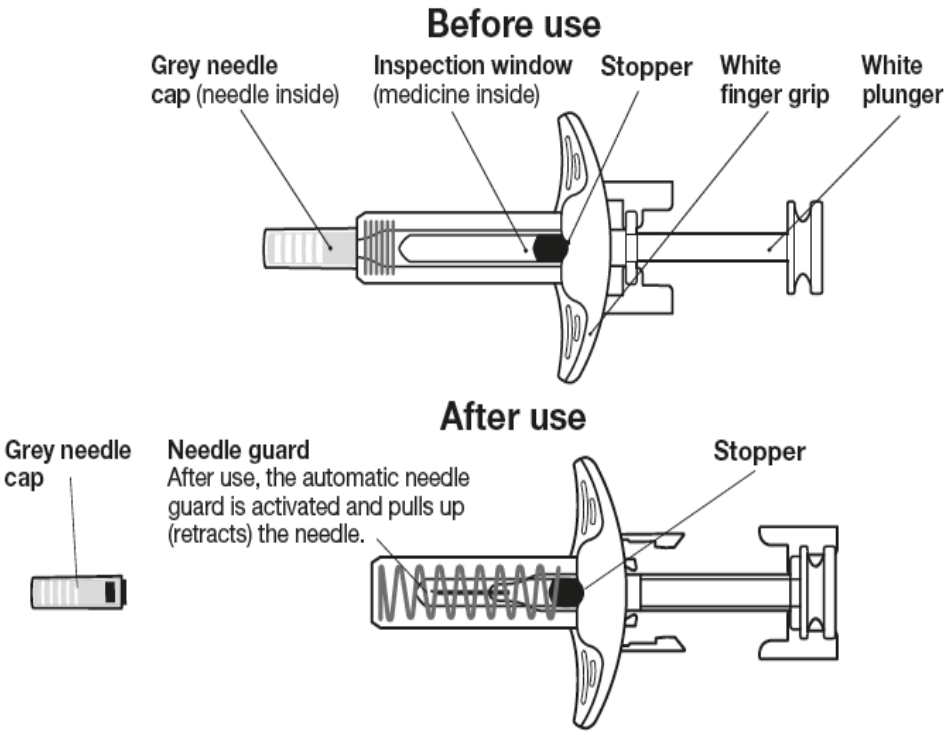
- It has been frozen
- It has been dropped or damaged
- The security seal on the carton has been broken
- The expiration date (EXP) has passed

Do not:

- Shake EXDENSUR syringe
- Share or reuse your syringe
- Expose your syringe to heat

If any of these happen, dispose of used pre-filled syringe according to local requirements and use a new EXDENSUR syringe. **Keep out of the sight and reach of children. Contains small parts.**

Get to Know Your EXDENSUR pre-filled Syringe



Storage

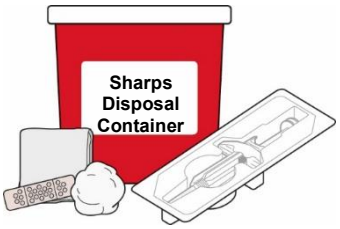
Syringe Stored In Carton
Store EXDENSUR in a refrigerator (2°C to 8°C) in the original carton until you are ready to use it. **Do not** freeze.

An unopened carton of EXDENSUR may be kept at room temperature up to 30°C for a maximum of 7 days. After being brought to room temperature, EXDENSUR must be used within 7 days or dispose of the syringe according to local requirements.

Syringe Removed From Carton
After the EXDENSUR syringe is out of the carton, it must be used within 8 hours or dispose of according to local requirements. **Do not** place back in the refrigerator.

A. Prepare

A1

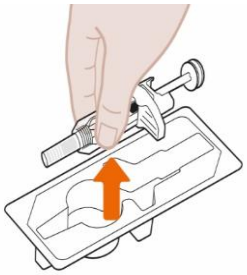


Gather supplies

Supplied
- EXDENSUR syringe

Not supplied
- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container (See Section C for disposal instructions).

A2



Take the **syringe out** of the tray

Take the carton containing your syringe out of the refrigerator

- Remove the tray from the carton and peel off the clear film cover from the corner of the tray.
- Holding the **middle** of the syringe (near the inspection window), carefully take the syringe out of the tray.
- **Do not** remove the grey needle cap at this step.

A3

Check the **Expiration date** and the **medicine**

Check your syringe

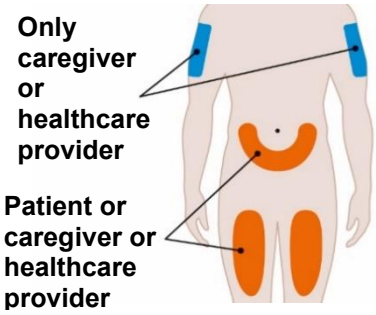
- Check the expiration date. **Do not** use if the expiration date has passed.
- Look at the medicine in the pre-filled syringe through the inspection window. The medicine should be clear and colourless to slightly yellow.
- **Do not** inject if this medicine is cloudy, discoloured, or has particles.
- It is normal to see air bubbles. You don't need to do anything about it.
- **Do not** shake the syringe.

A4

Wait 30 minutes

- **Do not** remove the grey needle cap.
- Place the syringe on a clean, flat surface away from direct sunlight and out of the sight and reach of children.
- **Wait 30 minutes** to bring to room temperature before you inject. Cold medicine is more painful to inject.
- **Do not** warm the syringe in a microwave, hot water, or direct sunlight.
- **Do not** use the syringe if it has been left out of the carton for more than 8 hours.

A5



Choose your injection site

- If you are giving yourself the injection, you can inject into your thighs or stomach (abdomen).
- A caregiver can inject into the upper arm, thigh, or abdomen.
- **Do not** inject yourself in the upper arm, as it is more difficult to avoid syringe movement during the injection.
- **Do not** inject where the skin is bruised, tender, red, or hard.
- **Do not** inject within 2 inches (5 cm) of your belly button.

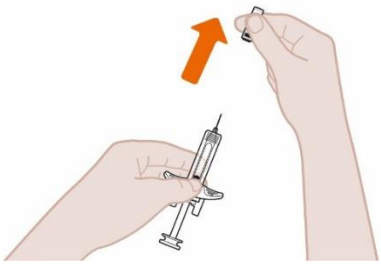
A6

Clean the injection site

- Wash your hands with soap and water.
- Clean the injection site with an alcohol swab. Allow skin to air dry.
- **Do not** fan or blow on the cleaned injection site.
- **Do not** touch the cleaned injection site again until you have finished your injection.

B. Inject

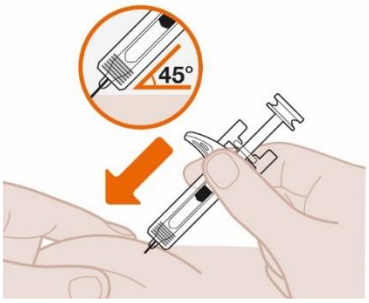
B1



Pull off the grey needle cap

- Holding the middle of the syringe, remove the grey needle cap from the syringe by pulling it straight off, away from the needle (as shown). It may take some force to remove the grey needle cap.
- **Do not** handle the syringe by the white plunger while removing the grey needle cap.
- **Do not** let the needle touch any surface.
- **Do not** touch the needle.
- **Do not** try to remove any air bubbles from the syringe.
- **Do not** put the grey needle cap back onto the syringe. This could cause a needle stick injury.
- Inject within 5 minutes after you remove the grey needle cap.

B2



Position the syringe at the injection site

- Use your free hand to gently pinch the skin around the cleaned injection site.
- Keep pinching the skin throughout the injection.
- **Do not** handle the syringe by the white plunger while inserting the needle into the pinched skin.
- Hold the **middle** of the syringe and insert the entire needle into the pinched skin at a 45 degree angle, as shown.

B3

Start the injection

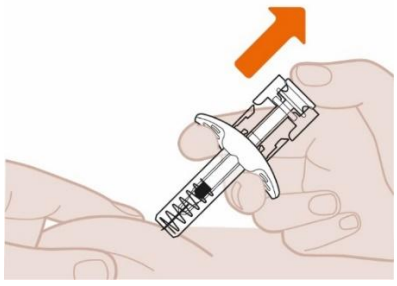
- Move your thumb to the white plunger and use your other fingers to hold onto the white finger grip, as shown.
- Slowly push down on the white plunger to inject the full dose.

B4

Fully press the white plunger

- Make sure the white plunger is pushed all the way down until the stopper reaches the bottom of the syringe and all of the medicine is injected.

B5



Slowly lift thumb after injection completes

- Slowly lift your thumb up. This will allow the white plunger to come up and the needle to automatically pull up (retract) into the needle guard.
- After removing the syringe from the injection site, release the pinched skin.
- **Do not** rub the injection site.
- **Do not** put the grey needle cap back onto the syringe.
- There may be a small drop of blood at the injection site. This is normal. Press a cotton ball or gauze on the area and apply an adhesive bandage if you need it.

C. Throw away

- Dispose of the used syringe and grey needle cap, according to local requirements. Ask your doctor or pharmacist for advice if necessary.
- **Keep your used syringes and needle caps out of the sight and reach of children.**