

Package leaflet: Information for the user

EXDENSUR 100 mg solution for injection in pre-filled pen 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 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 pen 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 breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using 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 carton in order to protect from light.

The pre-filled pen 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 pen according to local requirements.

The pre-filled pen 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 pen.

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

Marketing Authorisation Holder

GlaxoSmithKline UK Limited
79 New Oxford Street
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United Kingdom

Manufacturer

Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations)
Harmire Road
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 19494/0328

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

This leaflet was last revised in November 2025.

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

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 EXDENSUR pre-filled pen, it is important that your healthcare provider explains your EXDENSUR dosing instructions, and shows you (or your caregiver) how to use the pen 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 pen 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 pen. If you do not follow these instructions, you may not get all your medicine.

Do not use EXDENSUR pen 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

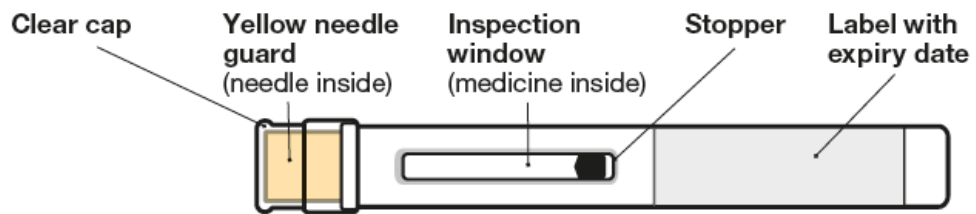
Do not:

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

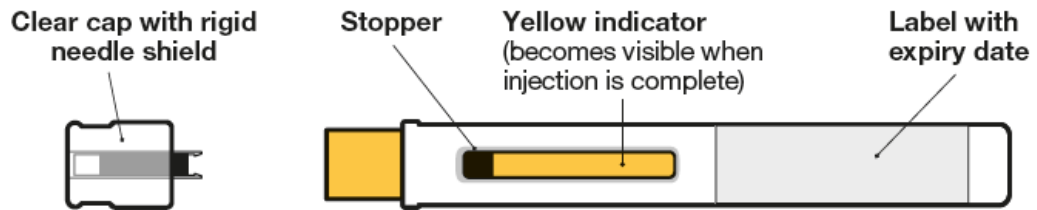
If any of these happen, dispose of used EXDENSUR pen according to local requirements and use a new EXDENSUR pen. **Keep out of the sight and reach of children. Contains small parts.**

Get to Know the EXDENSUR pre-filled Pen

Before use



After use



Storage

Pen 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 pen 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 pen according to local requirements.

Pen Removed From Carton

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

A. Prepare

A1



Gather supplies

Supplied

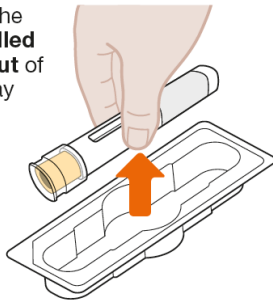
- EXDENSUR pen

Not supplied

- Alcohol swab
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container (See Section C for disposal instructions.)

A2

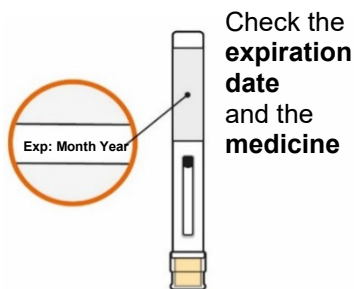
Take the pre-filled pen out of the tray



Take the carton containing your pen 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 pen (near the inspection window), carefully take the pen out of the tray.
- **Do not** remove the clear needle cap at this step.


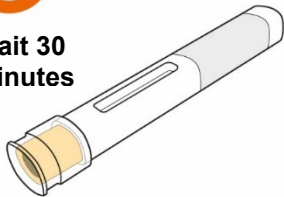
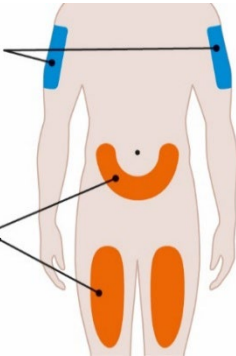


A3



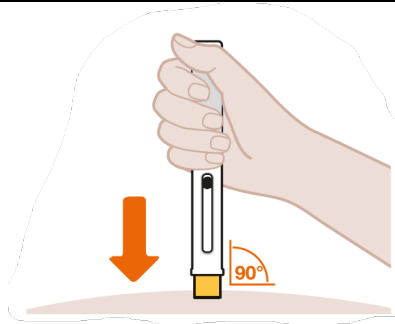
Check the expiration date and the medicine

Check your pen

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

<div data-bbox="199 174 308 286">A4</div> <div data-bbox="363 241 453 327">  </div> <div data-bbox="373 342 475 405"> <p>Wait 30 minutes</p> </div> <div data-bbox="403 315 687 510">  </div>	<p>Wait 30 minutes</p> <ul style="list-style-type: none"> • Do not remove the clear cap. • Place the pen on a clean, flat surface away from direct sunlight and out of the reach of children. • Wait 30 minutes to bring to room temperature before you inject. Cold medicine is more painful to inject. • Do not warm EXDENSUR pen in a microwave, hot water, or direct sunlight. • Do not use the EXDENSUR pen if it has been left out of the carton for more than 8 hours.
<div data-bbox="199 622 308 734">A5</div> <div data-bbox="316 712 456 869"> <p>Only caregiver or healthcare provider</p> </div> <div data-bbox="308 891 467 1014"> <p>Patient or caregiver or healthcare provider</p> </div> <div data-bbox="467 701 703 1055">  </div>	<p>Choose your injection site</p> <ul style="list-style-type: none"> • 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 pen 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.
<div data-bbox="199 1070 308 1182">A6</div> <div data-bbox="352 1081 687 1361">  </div>	<p>Clean the injection site</p> <ul style="list-style-type: none"> • 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.
<p>B. Inject</p>	
<div data-bbox="199 1496 308 1608">B1</div> <div data-bbox="352 1563 687 1821">  </div>	<p>Pull off the clear cap</p> <ul style="list-style-type: none"> • Remove the clear cap by pulling it straight off, away from the yellow needle guard. It may take some force to remove the clear cap. Do not twist the cap. • Do not press the yellow needle guard. Do not put the cap back on the pen. This could accidentally start the injection. • You may see a drop of medicine at the end of the needle. This is normal. • Inject as soon as possible and within 5 minutes after you remove the clear cap.

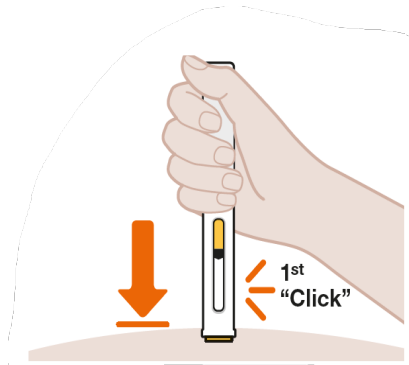
B2



Position the pen at the injection site

- Place the yellow needle guard flat against your skin.
- Make sure you can see the inspection window.

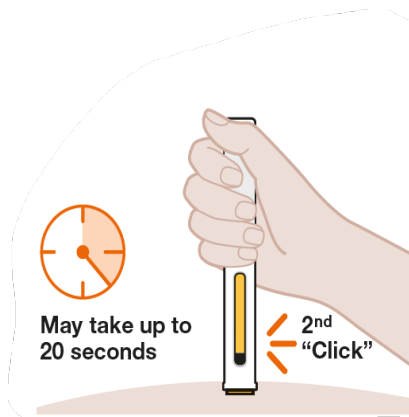
B3



Press firmly to start the injection, do not lift

- The yellow needle guard will slide up into the pen.
- You may hear a “click” that tells you the injection has started.
- Keep the pen held down against the skin. **Do not** lift or move the pen until the injection is complete.
- The yellow indicator will move down through the inspection window during the injection.
- **Do not** use the pen if the yellow needle guard does not slide up into the pen. Throw away the pen and clear cap according to local requirements.

B4



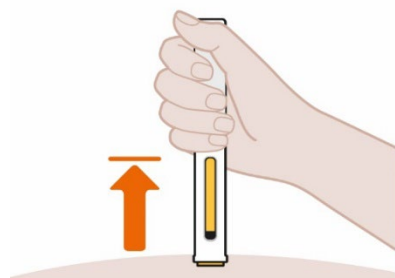
Continue to hold down, check the injection is complete before lifting

Your injection is done when you hear the second “click”. You must wait for the injection to complete before removing the pen to ensure you receive the full dose of medicine. Injection may take up to 20 seconds.

If you do not hear the second “click”, check the following before removing the pen:

- The inspection window is filled with the yellow indicator.
- The black stopper has stopped moving.
→ If the pen is lifted too soon, you may see a stream of medicine coming out. If this happens you may have not received the full dose. Call your doctor.

B5



Lift pen after injection completes

- **Do not** rub the injection site.
- **Do not** put the clear cap back onto the EXDENSUR pen.
- 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.

→ if you think that you have not received the full dose, call your doctor for assistance.

C. Throw away



Dispose of your used pen and clear cap, according to local requirements. Ask your doctor or pharmacist for advice if necessary.

Keep your used pens and needle caps out of the sight and reach of children.