

EXDENSUR

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I receiving EXDENSUR?

EXDENSUR contains the active ingredient depemokimab. EXDENSUR is used to treat severe asthma in adults and adolescents over 12 years of age who are on medium- to high-dose inhaled corticosteroids (ICS) plus another asthma controller. EXDENSUR is also used to treat Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) in adults.

For more information, see Section [1. Why am I receiving EXDENSUR?](#) in the full CMI.

2. What should I know before I receive EXDENSUR?

Talk to your doctor if you have any other medical conditions, take any other medicines, have ever had an allergic reaction to depemokimab or any of the ingredients listed at the end of the CMI, have a parasitic infection, or experienced worsening symptoms during treatment. Talk to your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I receive EXDENSUR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EXDENSUR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is EXDENSUR given?

- The recommended dose is 100 mg. You will be given 1 injection once every 6 months under the skin (subcutaneously).
- EXDENSUR is a solution for injection in a pre-filled pen (auto-injector) or pre-filled syringe (safety

syringe). The injection can be given either by you, your caregiver or a health professional.

More instructions can be found in Section [4. How is EXDENSUR given?](#) in the full CMI.

5. What should I know while receiving EXDENSUR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using EXDENSUR. • Call your doctor if your symptoms get worse while receiving injections of EXDENSUR.
Things you should not do	• Do not stop injections of EXDENSUR unless your doctor advises you to. • Do not suddenly stop taking your medicines for asthma or CRSwNP once you have started EXDENSUR.
Driving or using machines	• Be careful driving or operating machinery until you know how EXDENSUR affects you.

Looking after your medicine	• Store at 2°C to 8°C. Refrigerate. Do not freeze. • Store in the original carton to protect from light.
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For more information, see Section [5. What should I know while receiving EXDENSUR?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include itching, headache, tiredness, rash, or injection site reactions (pain, redness, swelling or itching at the site of injection). Serious side effects include allergic reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EXDENSUR

Active ingredient: *depemokimab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EXDENSUR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EXDENSUR.**

Where to find information in this leaflet:

- [1. Why am I receiving EXDENSUR?](#)
- [2. What should I know before I receive EXDENSUR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is EXDENSUR given?](#)
- [5. What should I know while receiving EXDENSUR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving EXDENSUR?

EXDENSUR contains the active ingredient depemokimab. Depemokimab is an ultra-long-acting monoclonal antibody, a type of protein designed to recognise a specific substance in the body.

EXDENSUR is used to treat severe asthma in adults and adolescents over 12 years of age who are on medium- to high-dose inhaled corticosteroids (ICS) plus another asthma controller. EXDENSUR is also used to treat Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) in adults over 18 years of age.

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

Asthma

Inflammation in your lungs and airways leads to the signs and symptoms of asthma. EXDENSUR helps prevent severe asthma attacks (exacerbations).

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

EXDENSUR does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore, EXDENSUR should not be used to treat such symptoms.

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) and the size of your nasal polyps. EXDENSUR may help with nasal discharge, loss of smell, the use of oral corticosteroid medicines and may prevent surgery for your nasal polyps.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

2. What should I know before I receive EXDENSUR?

Warnings

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- you are allergic to depemokimab, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

- have had an allergic reaction to any other medicine before.
- have an existing parasitic infection or live in a region where these infections are common or if you are travelling to such a region. EXDENSUR may weaken your resistance to such infections. Parasitic infections should be treated prior to starting treatment with EXDENSUR.
- experience worsening asthma symptoms while receiving injections.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Your doctor has weighed any risks of you using EXDENSUR against the benefits they expect it will have for you. You can talk to your doctor about the risks and benefits of using this medicine.

Action Plan

When EXDENSUR is used for the treatment of asthma, your doctor should give you a personal Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have sudden attacks of breathlessness or wheezing.

Ask your doctor or pharmacist if you have any questions about your Action Plan.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not receive EXDENSUR without asking your doctor.

Your doctor will consider the benefit to you and the risk to you and your baby of being given EXDENSUR during your pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether the ingredients of EXDENSUR can pass into breast milk.

Children

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

3. What if I am taking other medicines?

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

Do not suddenly stop taking your medicines for 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EXDENSUR.

4. How is EXDENSUR given?

How to use EXDENSUR

EXDENSUR is given by injection under the skin (subcutaneously).

EXDENSUR is available in a pre-filled pen (auto-injector) and a pre-filled syringe (safety syringe).

EXDENSUR can be given either by you, your caregiver or a healthcare professional.

- Your doctor or nurse will decide if you or your caregiver can inject EXDENSUR. If appropriate, they will 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 inject EXDENSUR at these sites or into your upper arm.
- You must not give injections into areas where the skin is tender, bruised, red, or hard.
- See the Instructions for Use leaflet in the carton for step-by-step instructions.

Contact your healthcare provider if you experience difficulties during the self-administration or have any concerns regarding an incomplete injection.

How much to use

Asthma

Adults and adolescents aged 12 years and over

- The recommended dose for adults and adolescents aged 12 years and over is 100 mg.
- You will be given 1 injection once every 6 months under the skin (subcutaneously).

CRSwNP

Adults aged 18 years and over

- The recommended dose for adults aged 18 years and over is 100 mg.
- You will be given 1 injection once every 6 months under the skin (subcutaneously).

Follow the instructions provided and use EXDENSUR until your doctor tells you to stop.

If you miss a dose of 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 or pharmacist.

If you receive too much EXDENSUR (overdose)

If you think that you or anyone else has received too much EXDENSUR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while receiving EXDENSUR?

Things you should do

- If you have an Action Plan for your asthma that you have agreed with your doctor, follow it closely at all times.

- Remind any doctor, dentist or pharmacist you visit that you are using EXDENSUR, especially if you are about to be started on any new medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using EXDENSUR.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away:

- If your symptoms get worse while receiving injections of EXDENSUR. Some people get asthma-related side effects or their asthma may become worse, during treatment with EXDENSUR.

Things you should not do

- 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.
- Do not suddenly stop taking your medicines for asthma or CRSwNP once you have started EXDENSUR.

Ask your doctor, pharmacist or nurse if you have any further questions about the use of this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EXDENSUR affects you.

The possible side effects of EXDENSUR are unlikely to affect your ability to drive or use machines.

Looking after your medicine

Store at 2°C to 8°C (Refrigerate. Do not freeze).

Store in the original carton to protect from light.

The pre-filled pen and 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. Discard if left out of the refrigerator for more than 7 days.

The pre-filled pen and pre-filled syringe must be used within 8 hours once removed from the carton. Discard if not used within 8 hours.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Like all medicines, EXDENSUR can cause side effects, although not everybody gets them. The side effects caused by EXDENSUR are usually mild to moderate

but can occasionally be serious and may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection related reactions: • Headache, feeling tired or rash around the time of injection • Injection site reaction (i.e. pain, redness, swelling or itching at the site of the injection) Skin disorders: • Itching	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects	What to do
Immune disorders: • Allergic reactions These reactions generally occur within hours after the medicine is	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
administered, but in some instances symptoms can have a delayed onset of up to several days. If you think you are having an allergic reaction to EXDENSUR tell your doctor or a nurse immediately. Discuss ongoing use of this medicine with your treating physician urgently.	notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What EXDENSUR contains

Active ingredient (main ingredient)	depemokimab
Other ingredients (inactive ingredients)	trehalose dihydrate arginine hydrochloride histidine hydrochloride monohydrate histidine polysorbate 80 disodium edetate water for injections

Check with your doctor if you are allergic to any of these ingredients.

What EXDENSUR looks like

Pre-filled pen (auto-injector) (AUST R 486145)

Each pre-filled pen contains 100 mg of depemokimab.

EXDENSUR is supplied as a colourless, yellow to brown, clear to opalescent solution in a 1 mL siliconised, Type I glass syringe with 0.5 inch (12.7 mm), 29-gauge, stainless steel needle assembled into an auto-injector.

EXDENSUR is available in a carton containing 1 single-use pre-filled pen.

Pre-filled syringe (safety syringe) (AUST R 486146)

Each pre-filled syringe contains 100 mg of depemokimab.

EXDENSUR is supplied as a colourless, yellow to brown, clear to opalescent solution in a 1 mL siliconised, Type I glass syringe with 0.5 inch (12.7 mm), 29-gauge, stainless steel needle assembled into a syringe safety device with a needle guard.

EXDENSUR is available in a carton containing 1 single-use pre-filled syringe.

Who distributes EXDENSUR

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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