

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **EXDENSUR**

Depemokimab Injection

This Patient Medication Information is written for the person who will be taking **EXDENSUR**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **EXDENSUR**, talk to a healthcare professional.

What **EXDENSUR** is used for:

- **EXDENSUR** is used with other asthma medicines for the maintenance treatment of adults and adolescents 12 years of age and older with severe eosinophilic asthma that is not controlled with their current asthma medicine. Asthma is a chronic inflammatory disease of the lungs and airways that causes symptoms like shortness of breath, chest tightness, coughing and wheezing. Severe eosinophilic asthma is a type of asthma where patients have increased eosinophils in their lungs and airways. Eosinophils are a type of white blood cell that are associated with inflammation of the lungs and airways that can cause your asthma to get worse.

EXDENSUR is not used to treat asthma attacks (sudden difficulty breathing).

- **EXDENSUR** is used to treat Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) in adults. CRSwNP is a chronic inflammatory disease of your nose and sinuses that 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.

How **EXDENSUR** works:

EXDENSUR contains the active substance depemokimab.

Depemokimab is a monoclonal antibody (a type of specialized protein) that blocks the action of an inflammatory protein called interleukin (IL)-5 that plays a critical role in eosinophil inflammation. **EXDENSUR** reduces inflammation that plays a major role in asthma and CRSwNP.

Asthma

EXDENSUR helps prevent severe asthma attacks (exacerbations).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

EXDENSUR helps reduce symptoms of CRSwNP, including nasal congestion, and reduces the size of your nasal polyps.

The ingredients in **EXDENSUR** are:

Medicinal ingredients: depemokimab.

Non-medicinal ingredients: L-arginine hydrochloride, disodium edetate dihydrate, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, trehalose dihydrate, water for injections.

EXDENSUR comes in the following dosage forms:

A solution for subcutaneous injection in pre-filled pen or pre-filled syringe. Each pre-filled pen or pre-filled syringe contains 100 mg/mL of depemokimab.

Do not use EXDENSUR if:

- you are allergic to depemokimab or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take EXDENSUR.

- Medicines of this type (monoclonal antibodies) can cause severe allergic reactions such as anaphylaxis (skin rash (hives) or redness, swelling of the face or mouth (angioedema), becoming very wheezy, coughing or having difficulty breathing, suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)) when injected into the body. If you have had a similar reaction before, tell your healthcare professional before you are given EXDENSUR.
- 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. Talk to your healthcare professional if your asthma remains uncontrolled, or gets worse, after you start EXDENSUR treatment.
- Talk to your healthcare professional if you are taking, have recently taken, or might take any other medicines. 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 healthcare professional.

Talk about any health conditions or problems you may have, including if you:

- have an existing parasitic infection, live in a region where infections caused by parasites 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.

Pregnancy and breastfeeding:

- If you are pregnant, if you think you may be pregnant, or if you are planning to become pregnant, ask your healthcare professional about the risks of EXDENSUR before using this medicine.
- It is not known whether the ingredients of EXDENSUR can pass into breast milk. If you are breastfeeding, check with your healthcare professional before you use EXDENSUR.

Other warnings you should know about:

- EXDENSUR should not be given to children under 12 years of age for the treatment of severe asthma and should not be given to children and adolescents under 18 years of age for the treatment of CRSwNP.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take EXDENSUR:

- EXDENSUR is given by injection under the skin.
- EXDENSUR can be given either by you, your caregiver, or a healthcare professional.
- Your healthcare professional will decide if you can inject yourself, or if your caregiver can inject you, with EXDENSUR. If appropriate, your healthcare professional 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 also inject EXDENSUR into the back of your upper arm. Injections must not be given into areas where the skin is tender, bruised, red, or hard.
- Speak to your healthcare professional if you experience difficulties with injections given by yourself or your caregiver including if you have concerns regarding an incomplete injection.

Usual dose:

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 one (1) injection once every 6 months under the skin (subcutaneous).

CRSwNP

The recommended dose for adults is 100 mg. You will be given one (1) injection once every 6 months under the skin.

Overdose:

If you think you, or a person you are caring for, have taken too much EXDENSUR, contact a healthcare professional, hospital emergency department, regional poison control centre, or Health Canada's toll-free number at 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If your healthcare professional gives you your injection of EXDENSUR and you miss a planned dose, contact your healthcare professional 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 healthcare professional.

Do not stop injections of EXDENSUR unless your healthcare professional advises you to do so. Interrupting or stopping treatment with EXDENSUR may cause your symptoms to come back or become worse. **If your symptoms get worse while receiving injections of EXDENSUR call your healthcare professional.** If you have any further questions on the use of this medicine, ask your healthcare professional.

Possible side effects from using EXDENSUR:

These are not all the possible side effects you may have when taking EXDENSUR. If you experience any side effects not listed here, tell your healthcare professional.

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)

Tell your healthcare professional immediately if you get any of these symptoms, or if you notice any side effects not listed in this leaflet.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Unknown			
Anaphylaxis (Sudden, severe allergic reaction): <ul style="list-style-type: none">• skin rash (hives) or redness• swelling, sometimes of the face or mouth (angioedema)• becoming very wheezy, coughing or having difficulty breathing• suddenly feeling weak or light headed (may lead to collapse or loss of consciousness)			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep out of reach and sight of children.
- Do not use EXDENSUR after the expiry date stated on the label and carton. The expiry date is the last day of that month noted after the text EXP:.
- Store EXDENSUR in a refrigerator between 2°C to 8°C in the original carton until you are ready to use it.
- 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 the carton is opened. Discard if not used within 8 hours.
- Any unused medicinal product or waste material must be disposed of in accordance with local requirements.

If you want more information about EXDENSUR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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Instructions For Use – Pre-Filled Pen

INSTRUCTIONS FOR USE
EXDENSUR [ex-DEN-shur]
(depemokimab)
injection, for subcutaneous use
100 mg/mL

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

Read These Sections First

Before using your EXDENSUR pen, it is important that your healthcare provider explain your EXDENSUR dosing instructions, and show you (or your caregiver) how to use the pen the right way.

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

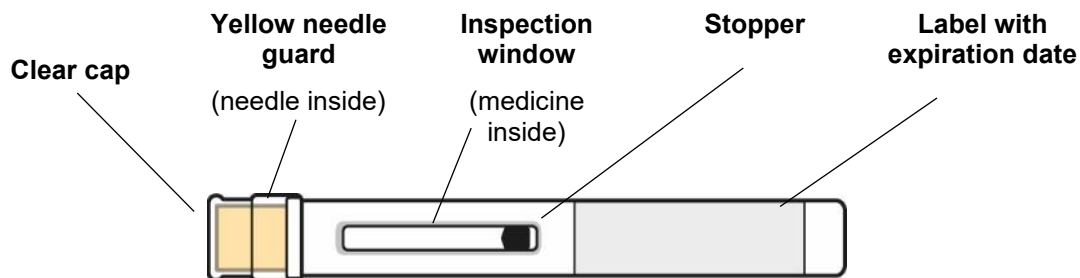
Do not:

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

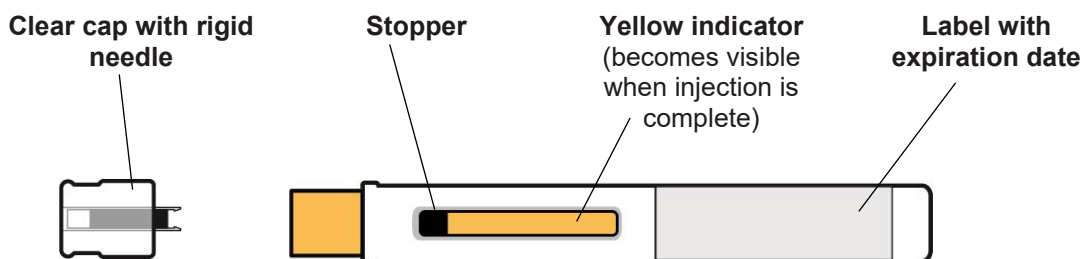
If any of these happen, dispose of the EXDENSUR pen according to local health and safety laws and use a new EXDENSUR pen. **Keep out of reach of children. Contains small parts.**

Get to Know the EXDENSUR Pen

Before Use



After Use



Storage

Pen Stored in Carton

Store EXDENSUR in a refrigerator between 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 health and safety laws.

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 health and safety laws. **Do not** place back in the refrigerator.

Keep out of reach of children. Contains small parts.

A. Prepare

A1



Gather Supplies

Supplied

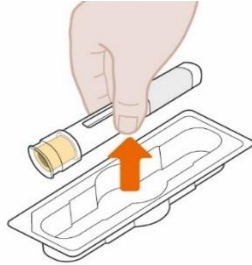
- EXDENSUR pen

Not Supplied

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

A2

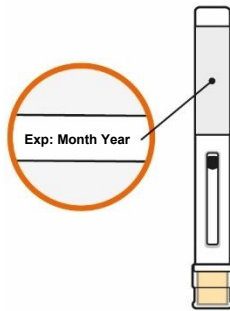
Take the **pre-filled pen** out of the tray



Take The Carton Containing Your Pen Out of the Refrigerator

- 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

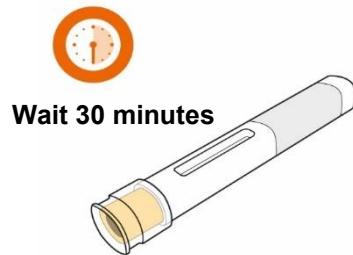


Check the **expiration date** and the **medicine**

Check Your Pen

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

A4



Wait 30 minutes

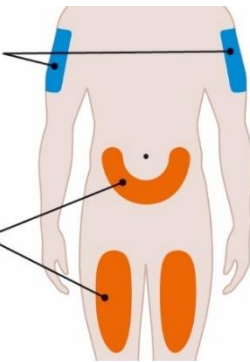
Wait 30 minutes

- **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.

A5

Only **caregiver or healthcare provider**


Patient or caregiver or healthcare provider



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 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.

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

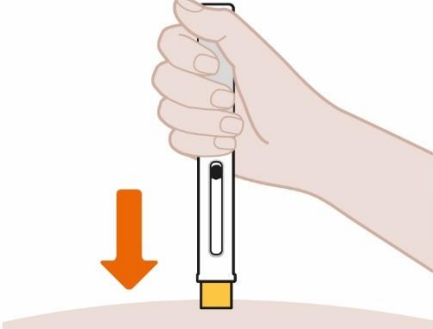
B1



Pull Off the Clear Cap

- 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** 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 within 5 minutes after you remove the clear cap.

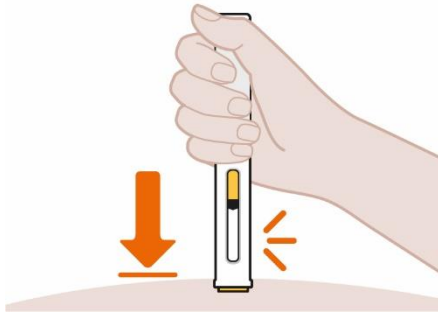
B2



Position the Pen at the Injection Site

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

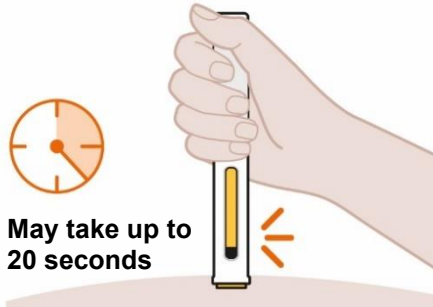
B3



Press Firmly to Start the Injection

- 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 during the injection.
- 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 health and safety laws.

B4



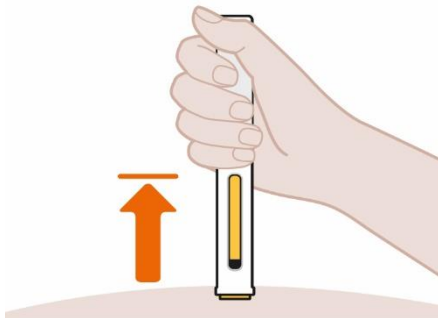
Continue to Hold Down

Your injection is done when you hear the second click. Injection may take up to 20 seconds.

If you do not hear the second click, check that:

- The inspection window is filled with the yellow indicator.
- The black stopper has stopped moving.

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.

C. Throw Away



Dispose of the used pen and needle 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

Instructions For Use – Pre-Filled Syringe

INSTRUCTIONS FOR USE

EXDENSUR [ex-DEN-shur]

(depemokimab)

injection, for subcutaneous use

100 mg/mL

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

Read These Sections First

Before using your EXDENSUR syringe, it is important that your healthcare provider explain your EXDENSUR dosing instructions, and show you (or your caregiver) how to use the syringe the right way.

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 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

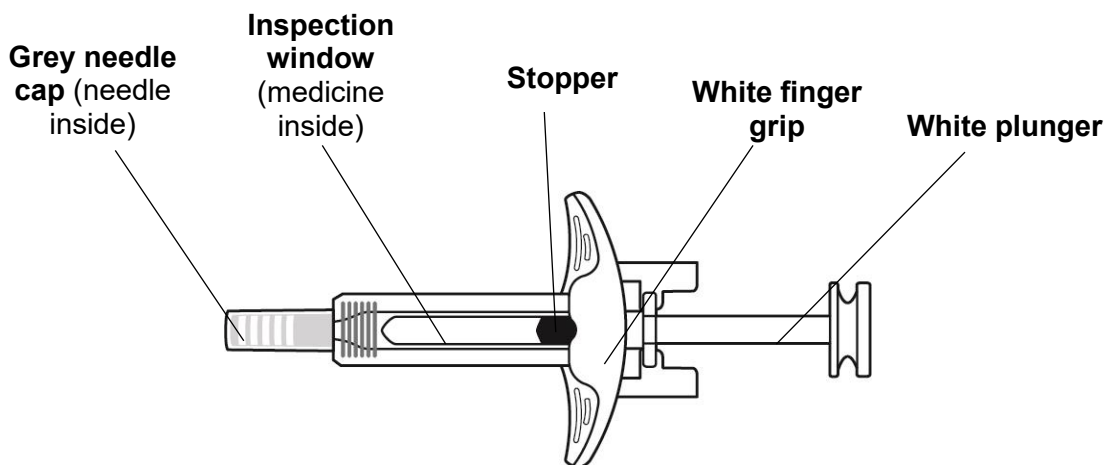
Do not:

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

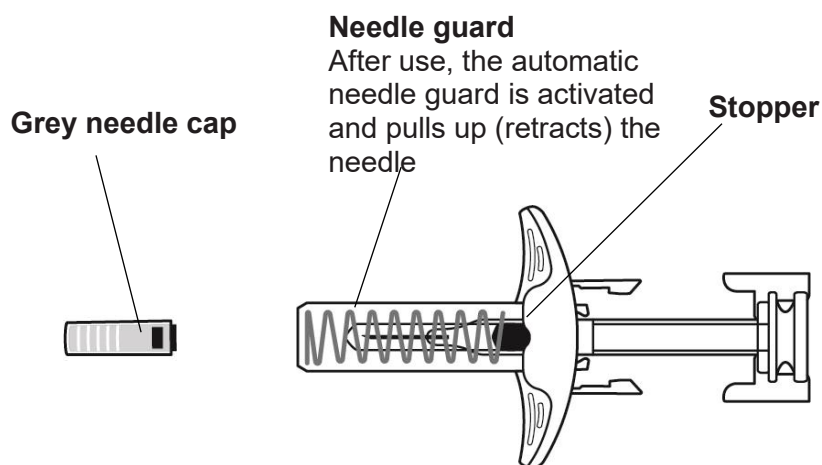
If any of these happen, dispose of the EXDENSUR syringe according to local health and safety laws and use a new EXDENSUR syringe. **Keep out of reach of children. Contains small parts.**

Get to Know Your EXDENSUR Syringe

Before Use



After Use



Storage

Syringe Stored in Carton

Store EXDENSUR in a refrigerator between 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 health and safety laws.

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 health and safety laws. **Do not** place back in the refrigerator.

Keep out of reach of children. Contains small parts.

A. Prepare

A1



Gather Supplies

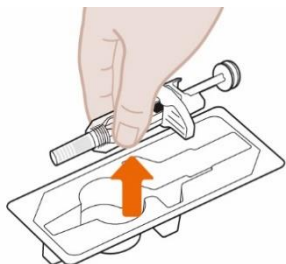
Supplied

- EXDENSUR syringe

Not Supplied

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

A2

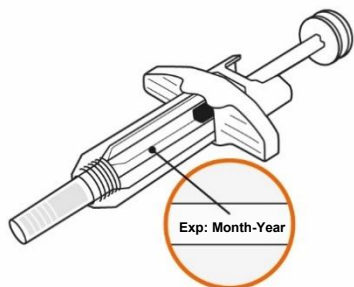


Take the **syringe** out of the tray

Take the Carton Containing Your Syringe Out of the Refrigerator

- 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

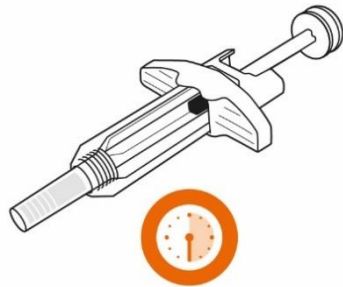


Check the **Expiration date** and the **medicine**

Check Your Syringe

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

A4



Wait 30 minutes

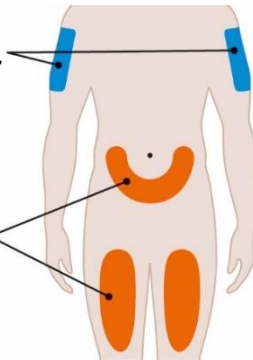
Wait 30 Minutes

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

A5

Only caregiver or healthcare provider

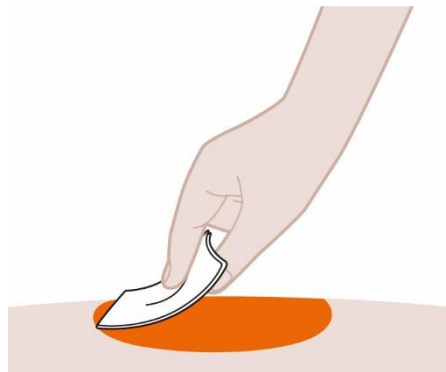
Patient or caregiver or healthcare provider



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

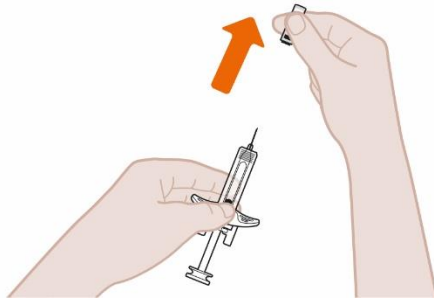


Clean the Injection Site

- 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

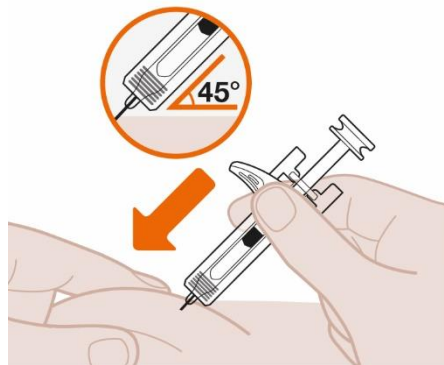
B1



Pull Off the Grey Needle Cap

- 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 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.

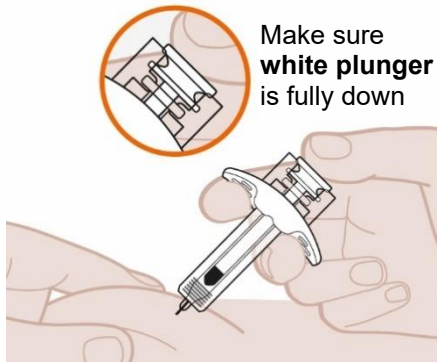
B3



Start the Injection

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

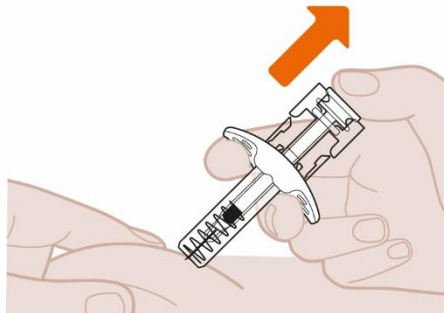
B4



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 EXDENSUR 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 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