

ANDEMBRY®▼(garadacimab)

A guide to ANDEMBRY® treatment

**This information is only for patients
who have been prescribed ANDEMBRY®**

ANDEMBRY® is a medicine used in patients aged 12 years and older with Hereditary Angioedema (HAE) to decrease angioedema attacks.

▼ 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 the booklet for how to report side effects.

Provided as an educational service to medicine by CSL Behring UK Ltd.

Please read all of this document carefully in line with the patient information leaflet.



What is Hereditary Angioedema (HAE)?

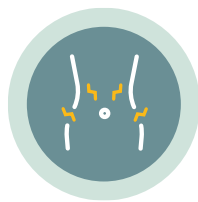
Hereditary Angioedema (HAE) is a non-allergic disease that causes episodes of swelling and pain, known as HAE attacks. These attacks can cause swelling and pain in different parts of the body including:



Hands and feet



Face, eyelids, lips or tongue



Stomach and gut



Genitals



Voice box (larynx) and throat, which may make breathing difficult

HAE attacks may be painful and disabling. Attacks of the throat or larynx may be dangerous or even life threatening

HAE is a condition that often runs in families, but some people may not have a family history. Three types of HAE are known, distinguished by underlying genetic mutations that affect the expression of a protein that circulates in your blood, called C1-esterase inhibitor (C1-INH).

Type I HAE

Low levels of C1-INH in the body

Type II HAE

Poorly functioning C1-INH

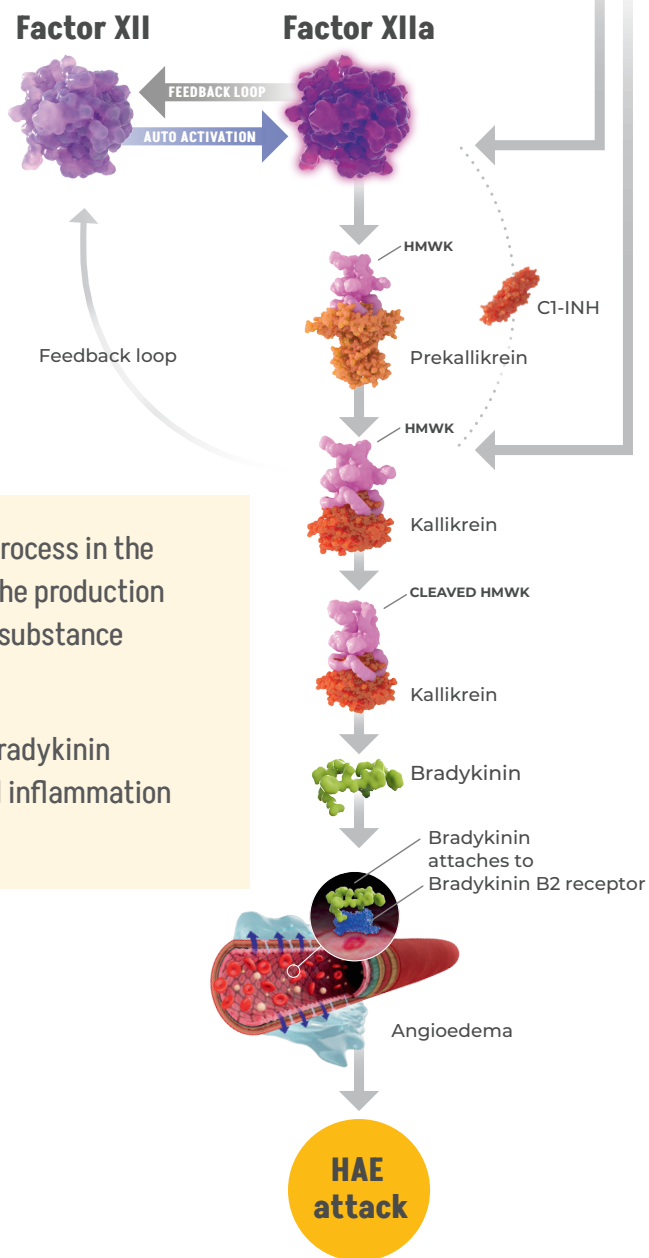
Type III HAE

HAE with normal functioning C1-INH

Type III HAE is a rare form of the condition. All three types produce the same clinical symptoms of localised swelling

What causes an HAE attack?

In those without HAE, C1-INH would stop the biochemical pathway here



C1-INH regulates a process in the body that controls the production of an inflammatory substance called bradykinin.

Overproduction of bradykinin causes swelling and inflammation in people with HAE.

What is ANDEMBRY® and how does it work?

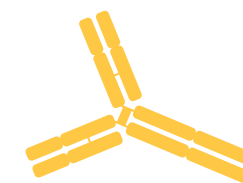
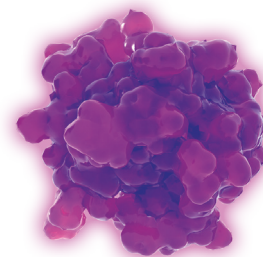


ANDEMBRY® is a medicine for patients aged 12 years and older with HAE to decrease HAE attacks

The active substance in ANDEMBRY®, garadacimab, blocks the activation of a protein known as Factor XIIa (FXIIa), which is involved in stimulating bradykinin production.

By blocking FXIIa activity, garadacimab reduces the level of bradykinin, thereby decreasing HAE attacks. Some subcategories of normal C1-INH HAE may not respond to treatment with garadacimab. Talk to your doctor if you have any concerns about your medicine.

Factor XIIa



ANDEMBRY®

This medicine inhibits Factor XIIa

What is in ANDEMBRY®?

What ANDEMBRY® contains

1.

The active substance is garadacimab, a monoclonal antibody. Each pre-filled pen contains 200 mg of garadacimab in a 1.2 mL solution.

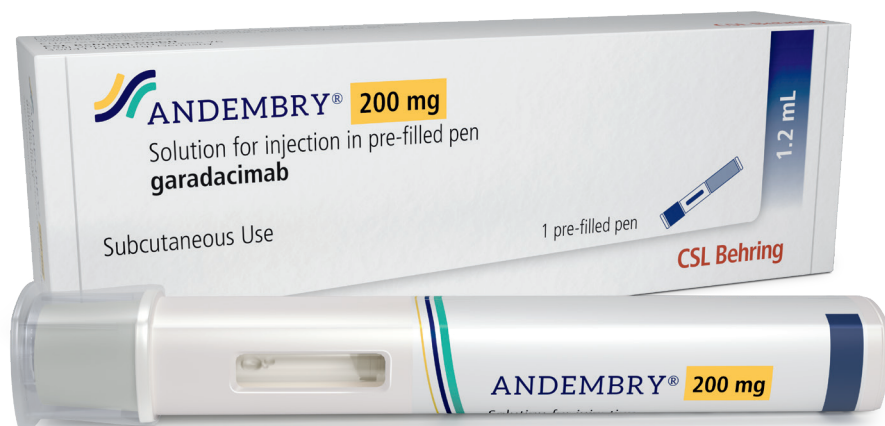
2.

The other ingredients are L-histidine, L-arginine monohydrochloride, L-proline, polysorbate 80 and water for injections.

What ANDEMBRY® looks like and the contents of the pack

This medicine is presented as a slightly opalescent to clear, brownish-yellow to yellow solution for injection in a pre-filled pen.

Each pack contains one 1.2 mL pre-filled pen.



What you need to know before you use ANDEMBRY®

Do not use this medicine

If you are allergic to garadacimab or any of the other ingredients in this medicine (listed on the page opposite)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine. If you have a severe allergic reaction to ANDEMBRY® (such as hives, tight chest, difficulty breathing, wheezing, hypotension, or anaphylaxis) tell your doctor, pharmacist or nurse **immediately**. Treat an HAE attack with your regular rescue medicine without taking additional doses of ANDEMBRY®

Children and adolescents

ANDEMBRY® is not recommended for use in children under 12 years of age. This is because it has not been studied in this age group

Laboratory tests

Tell your doctor if you are using ANDEMBRY® before you have laboratory tests to measure how well your blood is clotting. This is because ANDEMBRY® may interfere with some laboratory tests, leading to inaccurate results

Keeping a record

Every time you take a dose of ANDEMBRY®, write down the name and batch number of the medicine. This is so that you keep a record of the batches used

Other medicines and ANDEMBRY®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. ANDEMBRY® is not known to affect other medicines or be affected by other medicines

The information you need to know before taking ANDEMBRY® continues on the next page

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before starting ANDEMBRY®. There is limited information on the safety of ANDEMBRY® during pregnancy and breastfeeding. Your doctor will discuss with you the risks and benefits of taking this medicine

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines

This medicine contains:



Polysorbate 80

This medicine contains 0.24 mg of polysorbate 80 in each 200 mg/1.2 mL which is equivalent to 0.2 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.



Proline

This medicine contains 19.3 mg of proline in each 200 mg/1.2 mL which is equivalent to 16.1 mg/mL. Proline may be harmful for patients with hyperprolinaemia, a rare genetic disorder in which proline builds up in the body. If you (or your child) have hyperprolinaemia, **do not** use this medicine unless your doctor has recommended it.



Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose of solution, that is to say essentially “sodium-free”.

How to use ANDEMBRY®

ANDEMBRY® is provided in a single-use pre-filled pen

Your treatment will be started and managed under the supervision of a doctor experienced in the care of patients with HAE. If you inject this medicine yourself or if your caregiver injects it, you or your caregiver must carefully read and follow the steps in the ‘How to use ANDEMBRY®’ section.



Dosing



The recommended dose of this medicine in adults and adolescents aged 12 years and older is an initial loading dose of 400 mg, given as two 200 mg injections under the skin (subcutaneously) on the first day of treatment. After this, it is given as one 200 mg injection, once a month.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure or have any further questions on the use of this medicine. 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.

**Read and keep this leaflet.
You may need to read it again**

- ANDEMBRY® is for injection under the skin (subcutaneous injection) in the tummy (abdomen), thigh or upper arm
- The injection can be given by either yourself or a caregiver. Do not self-inject or allow a caregiver to inject you until you have been trained to inject the medicine
- A doctor, pharmacist or nurse should show you how to inject ANDEMBRY® properly before you use it for the first time. Use each pre-filled pen only once
- If the pre-filled pen does not perform as intended, tell your doctor, pharmacist or nurse **immediately**
- Rotation of the injection site is recommended

If you take more ANDEMBRY® than you should

Tell your doctor, pharmacist or nurse if you take too much ANDEMBRY®

If you miss a dose of ANDEMBRY®

If you miss a dose of ANDEMBRY®, inject your dose as soon as possible. If you are not sure when to inject ANDEMBRY® after a missed dose, ask your doctor, pharmacist or nurse

If you stop using ANDEMBRY®

It is important that you keep injecting ANDEMBRY® as instructed by your doctor, even if you feel better

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

Possible side effects



If you have a severe allergic reaction to this medicine with symptoms such as hives, tight chest, difficulty breathing, wheezing, hypotension or anaphylaxis, tell your doctor, pharmacist or nurse immediately

Like all medicines, ANDEMBRY® can cause side effects, although not everybody gets them. Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Common side effects

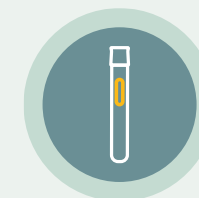
[May affect up to 1 in 10 people]



Abdominal pain



Headache



Injection-site reactions
(including redness, bruising,
itchiness and hives)



Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package 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 store. By reporting side effects, you can help provide more information on the safety of this medicine

What can I ask and what should I discuss at the next doctor's appointment?

To make the most of the limited time you have with your doctor, you may want to think about discussion points and questions you have about your treatment. In this section, you will find some important questions to think about, and topics of conversation to take with you to your next doctor's visit.

- Are there any special circumstances that I need to take into account when being treated with ANDEMBRY®?
- When can I expect the treatment to take effect?
- What is the aim of the treatment from your point of view?
- What can I do to support the success of the treatment?
- What signs or symptoms of side effects should I look out for?
- How often should I come in for a check-up?
- Do I have to take medication for the rest of my life?

These symptoms have improved/worsened...

The goals/expectations that I aim to achieve with my treatment are...

I'm worried about...

I'd like to discuss how to go about travelling/contraception/vaccination/conception while on ANDEMBRY®

Instructions for use

This pre-filled pen works differently to other injection devices. Read the Instructions for Use carefully before using it, and each time you get a new pre-filled pen. There may be new information. This information does not replace talking to your healthcare provider about your medical condition or treatment.

In adolescent patients, ANDEMBRY® should be given under the supervision of an adult.

Make sure you (or your caregiver, if you are allowing them to inject you) have been trained by your healthcare provider before you use this pre-filled pen for the first time.

The parts of the pre-filled pen (see Figure A)

Continue to the next sections to prepare and perform the injection.

Before use:

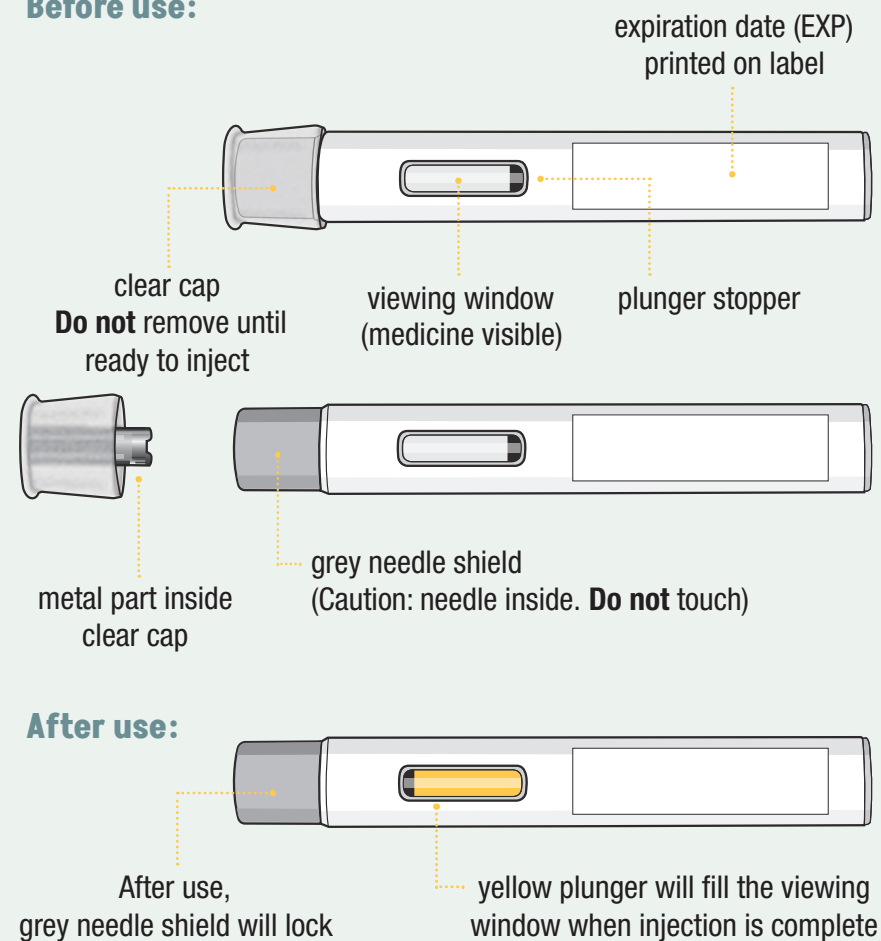


Figure A

Read the following safety information:

- Keep the pre-filled pen in its original carton box until use, to protect it from light
- **Do not** remove the clear pre-filled pen cap until you are ready to inject
- **Do not** put the clear pre-filled pen cap back on the pre-filled pen after it has been removed because this could start the injection and cause injury
- The pre-filled pen contains 1 dose and is for single-use only.
Do not try to reuse the same pre-filled pen
- **Do not** use the pre-filled pen if the expiry date has passed
- The pre-filled pen is for subcutaneous (under the skin) injection only
- **Do not** use the pre-filled pen if it has been dropped, looks damaged, has cracks or is leaking medicine. In these cases, inform your care team, throw away the pre-filled pen as described in Step 11 and use a new one
- **Do not** inject through clothing
- **Do not** touch or try to remove the grey needle shield at any time
- **Keep ANDEMBRY® out of sight and reach of children**

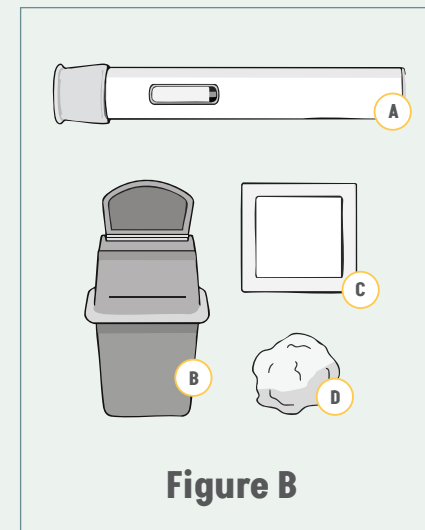
How to store ANDEMBRY®?

- Store the ANDEMBRY® pre-filled pen in a refrigerator, between 2°C to 8°C in its original carton until use, to protect it from light
- **Do not** freeze. If the pre-filled pen has been frozen, **do not** use the pre-filled pen, even if it is thawed
- Take the pre-filled pen out of the refrigerator 30 minutes before use, allowing it to reach room temperature
- If needed, for example when travelling, the pre-filled pen may be stored at room temperature (up to 25°C) for a single period of up to 2 months, but not beyond the expiry date
- If you decide to store the pre-filled pen at room temperature you must:
 - Write the date you first remove the pre-filled pen from the refrigerator in the space provided on the carton to help you keep track of how long it has been stored at room temperature

- **Do not** put the pre-filled pen back in the refrigerator after it has reached room temperature
- Throw away the pre-filled pen if it has been stored at room temperature for longer than 2 months (**see Step 11. Disposing of the pre-filled pen**)



Supplies needed for your pre-filled pen injection (see Figure B):



Included

- A** Single-dose pre-filled pen

Required but not included

- B** Sharps container or puncture-resistant container for disposal (**see Step 11. Disposing of the pre-filled pen**)
- C** Alcohol pad
- D** Cotton ball or gauze pad

Preparing for an injection

Do not remove the clear pre-filled pen cap until immediately before injection

Step 1:

Let the pre-filled pen reach room temperature

- Remove the pre-filled pen from the carton box and place it laying down on a **clean flat surface**
- Wait **30 minutes** for the medicine to reach room temperature if it was stored in the refrigerator (see Figure C). Injecting the medicine cold could be uncomfortable
- **Do not** try to speed up the warming process in any way. For example, **do not** warm it in a microwave, in hot water, or leave it in direct sunlight

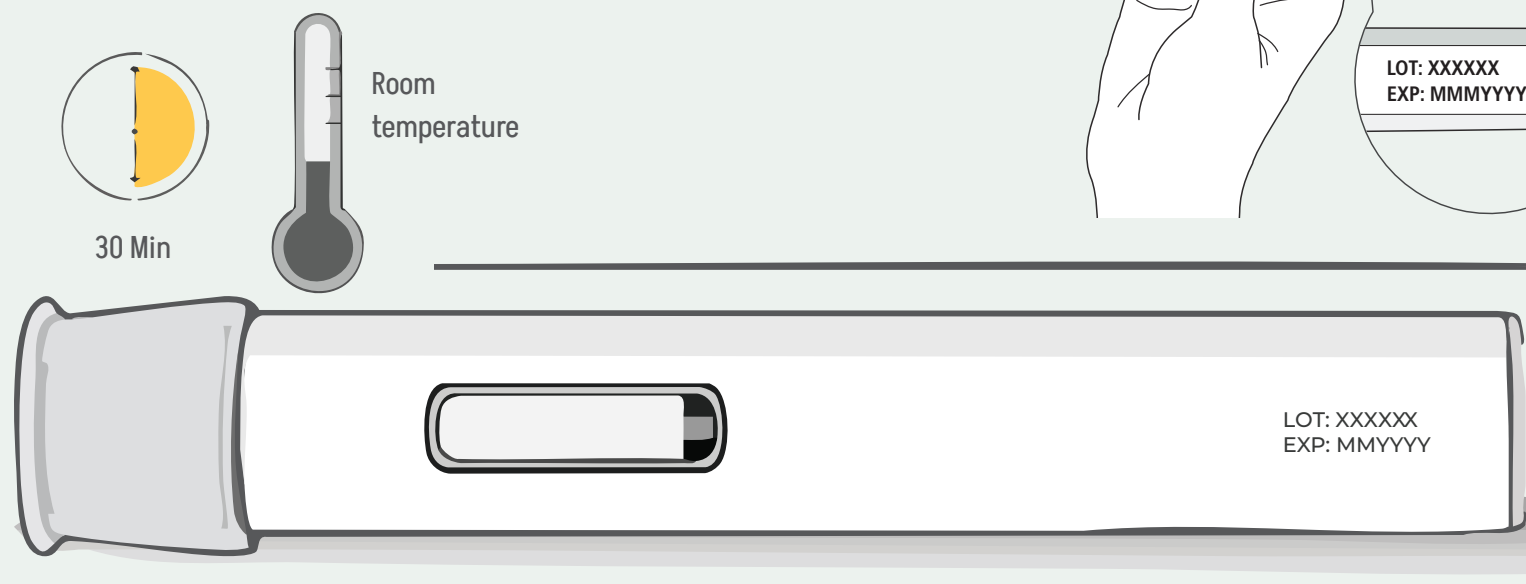


Figure C

Step 2:

Check the expiry date

- Check the expiry date on the pre-filled pen label (see Figure D)
- **Do not** use this medicine after the expiry date has passed. The expiry date is stated on the outer carton and label, after EXP. The expiry date refers to the last day of that month
- **Do not** use the pre-filled pen if it has been stored at room temperature for longer than 2 months
- If the expiry date has passed or if it has been stored at room temperature for longer than 2 months, then safely dispose of the pre-filled pen and get a new one (see **Step 11. Disposing of the pre-filled pen**)

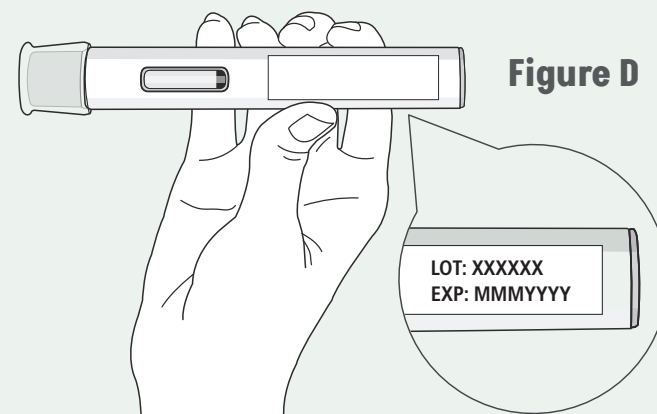
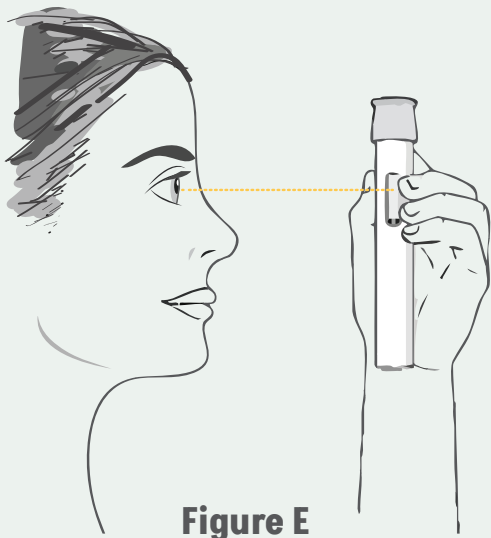


Figure D

Step 3:

Inspect the pre-filled pen and the medicine

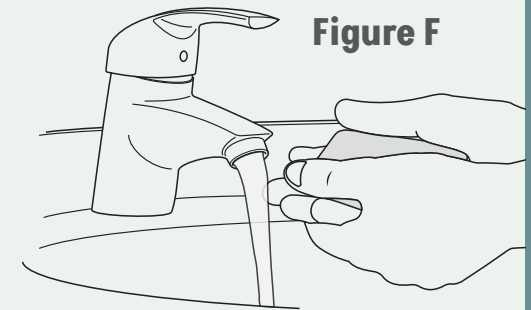
- **Check** the pre-filled pen **for damage**
- Check the medicine through the viewing window of the pre-filled pen (see Figure E)
- It is normal to see air bubbles. **Do not** try to remove air bubbles and do not shake the pre-filled pen
- The medicine should be a brownish-yellow to yellow liquid. It may appear slightly opalescent to clear
- **Do not** use the pre-filled pen, safely dispose of it and get a new one (see **Step 11. Disposing of the pre-filled pen**) if:
 - The medicine is discoloured or contains particles
 - The pre-filled pen looks damaged or has cracks
 - The pre-filled pen is leaking
 - The pre-filled pen has been dropped on a hard surface, even if it does not look damaged



Step 4:

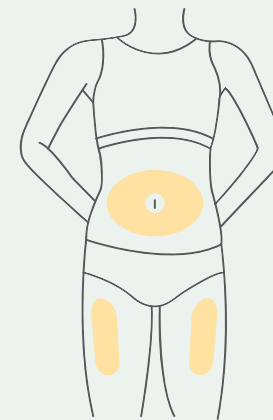
Clean your hands

- Wash your hands well with soap and water (see Figure F) or use hand sanitiser

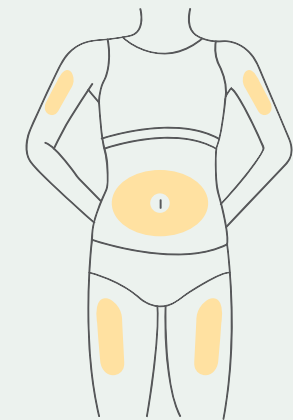


Step 5:

Select the injection site



Self-injection sites



Caregiver injection sites

Figure G

- Inject into the thigh or belly (abdomen) area, but stay 2cm away from the belly button (navel) (see Figure G)
- If somebody else (caregiver) gives you the injection, they can also use the upper arm. **Do not** try to inject into the upper arm yourself
- Change (rotate) your injection site with each injection. **Do not** inject in the same place multiple times if the skin is damaged
- **Do not** inject into the belly button, moles, scars or bruises, or into areas where the skin is tender, red, hard or injured

Step 6:

Prepare the injection site

- Clean the injection site with an alcohol pad (see Figure H)
- Let your skin dry on its own
- **Do not** fan or blow on the skin area that you cleaned
- **Do not** touch this area again before injecting

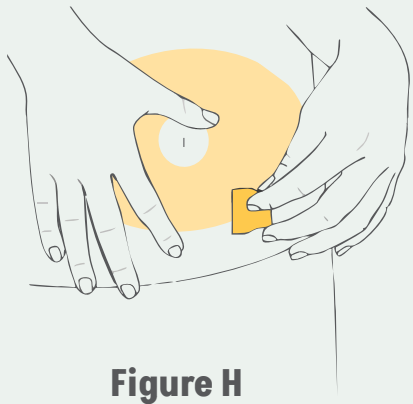


Figure H

Injecting the medicine with the pre-filled pen



Complete the injection without stopping

Read all steps first before beginning.

Do not remove the clear cap until you are ready to inject

Step 7:

Remove the clear pre-filled pen cap and dispose of the cap

- Hold the pre-filled pen with one hand and pull the **clear pre-filled pen cap straight off** with the other hand
- **Do not twist** the clear cap (see Figure I). If you cannot remove the clear cap, ask a caregiver for help or contact your healthcare provider
- The clear cap has a metal part inside; this is normal
- **Do not put the clear cap back** on after it has been removed because this could start the injection and cause injury
- Dispose of the clear cap in a sharps container or closed, puncture-resistant container

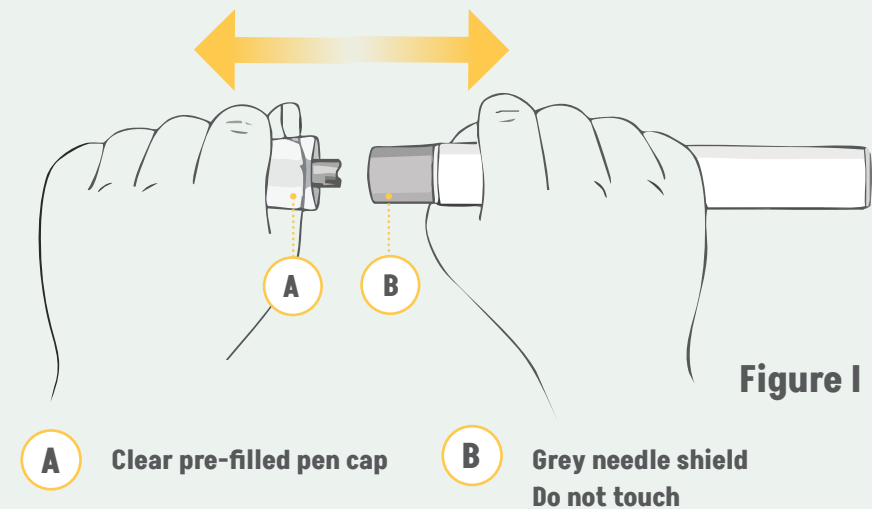


Figure I

A Clear pre-filled pen cap

B Grey needle shield
Do not touch

✗ **Do not** touch the grey needle shield of the pre-filled pen to avoid injury

✗ **Do not** put the pre-filled pen down after removing the clear cap

Step 8:

Pinch the skin and place the pre-filled pen on the injection site

Immediately after removing the clear pre-filled pen cap, complete the following steps without stopping:

- **Gently pinch** the area of cleaned skin around the injection site and hold the area firmly until the injection is complete (see Figure J)
- Place the pre-filled pen at a 90° angle on the cleaned injection site
- **Make sure you can see the viewing window**

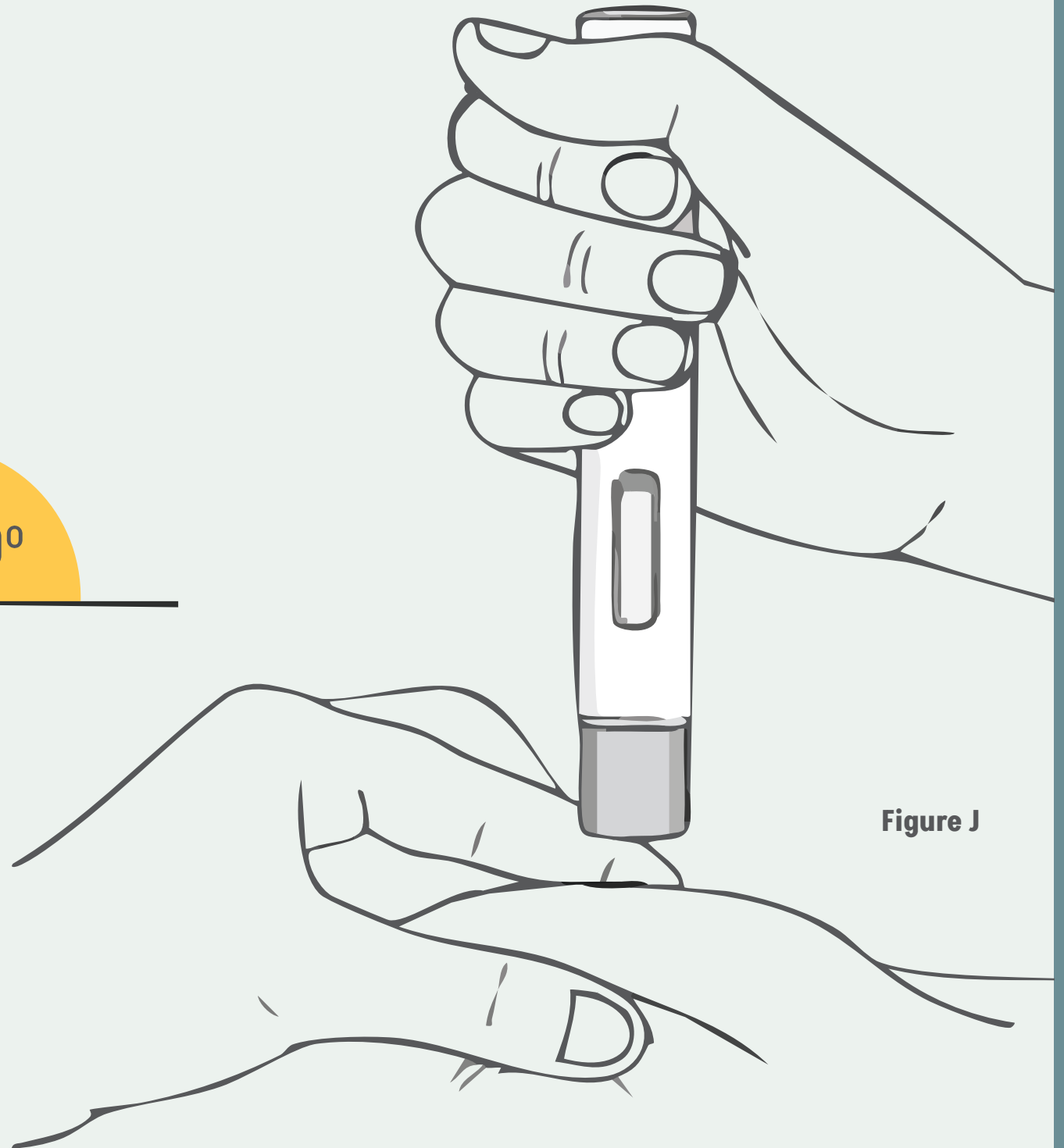
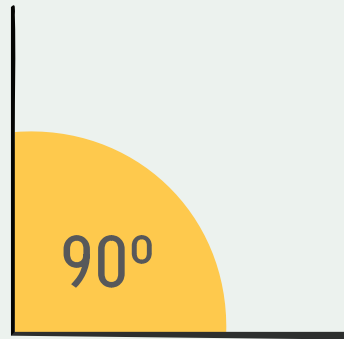


Figure J

Step 9:

Inject medicine (see Figure K)

You must **read all of Step 9** before injecting

- The injection may take up to 15 seconds

To ensure you receive a full dose, you must keep the pre-filled pen firmly pressed against your pinched skin until:

- The yellow plunger has stopped moving and filled the viewing window
- 5 seconds have passed after the 2nd "click"



Press the grey needle shield down firmly against the pinched skin to start the injection and keep pressing down until all the steps on the right hand side of this page are complete

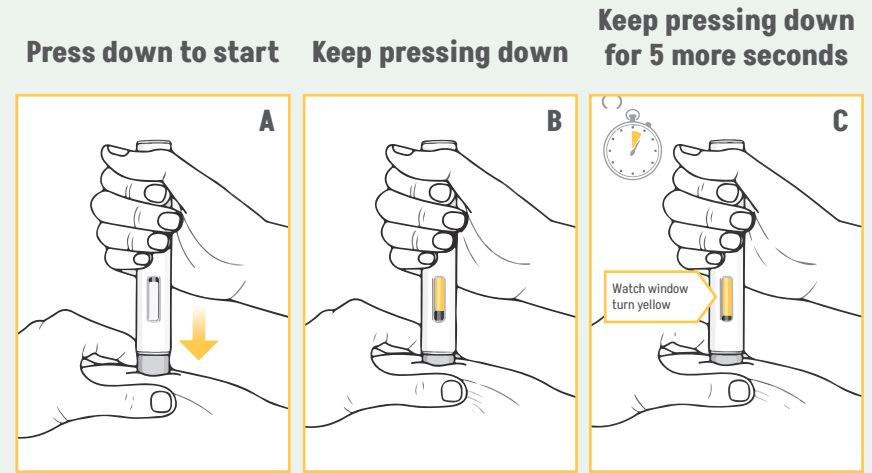


Figure K → First 'click' → Second 'click'

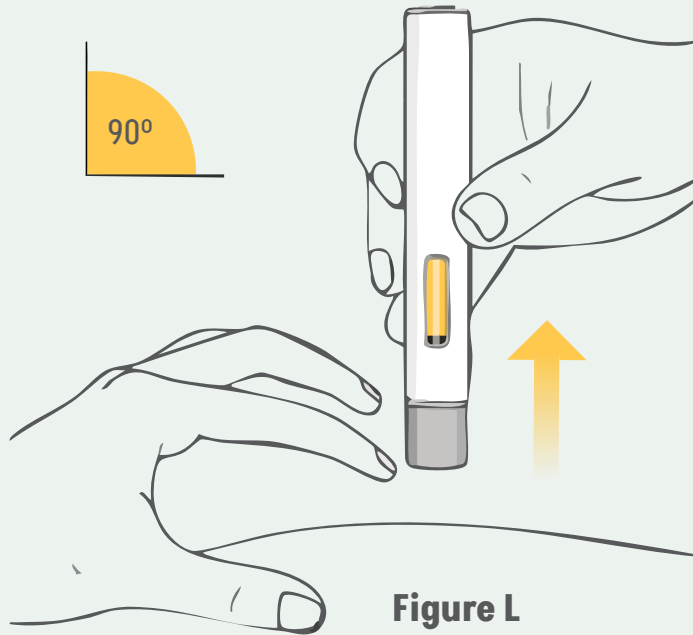
- A** **Press down to start** the injection and listen for a **first 'click'**
- The first 'click' means the injection has started
 - The yellow plunger will start moving in the viewing window
 - **Keep pressing** the pre-filled pen down
- B** **Keep pressing** the pre-filled pen down and watch the viewing window
- The window will turn yellow
 - You will hear a second 'click'
 - **Keep pressing** the pre-filled pen down
- C** **Keep pressing** the pre-filled pen **down** for **5 more seconds to make sure you get the full dose**

- ✗ **Do not** remove the pre-filled pen until the yellow plunger has stopped moving and completely filled the viewing window, and 5 seconds have passed after the second 'click'
- ✗ **Do not** remove, tilt or rotate the pre-filled pen during the injection

Step 10:

Release the pinch and remove the pre-filled pen

- Release the pinch and remove the pre-filled pen at a 90° angle from the skin (see Figure L)
- As the pre-filled pen is lifted from the skin, the grey needle shield will return to the original (before use) position and lock into place, covering the needle
- If there is a little bleeding at the injection site, you can press a cotton ball or gauze over the injection site



✗ **Do not** rub the injection site. If needed, you may cover the injection site with a small adhesive bandage



Important: If you think that you have not received the full dose, contact your healthcare provider right away

Step 11:

Disposing of the pre-filled pen

- **Do not** try to reuse the pre-filled pen
- After injecting your dose, put the pre-filled pen into a sharps container or closed, puncture-resistant container (see Figure M)

If you do not have a sharps container or closed, puncture-resistant container, you may use a household container that is:

- Made of heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- Upright and stable during use
- Leak-resistant
- Properly labelled to warn of hazardous waste inside the container

When your sharps container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps container. Ask your pharmacist or healthcare provider for more information on how to dispose of your sharps container.



- ✗ **Do not** dispose of your used sharps container in your household waste unless your local guidelines permit this
- ✗ **Do not** recycle your used sharps container
- ✗ **Do not** throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use

Step 12:

Keep track of your treatment

If required by your doctor, record your injection in a diary to help keep track of your medicine.



ANDEMBRY®

CSL Behring

CSL information:

Phone: 01444 447405

Email: medinfo@cslbehring.com

Address: CSL Behring UK Ltd
Haywards Heath, West Sussex

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Abbreviations: C1-INH, C1 esterase inhibitor; FXII, Factor Twelve; FXIIa, activated Factor Twelve; HAE, Hereditary Angioedema; HMWK, high-molecular-weight kininogen.

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