NovoThirteen® 2500 IU

catridecacog (rys)
Recombinant coagulation factor XIII

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NovoThirteen®. It does not contain all the available information. It does not take the place of talking to your doctor or healthcare professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoThirteen® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or healthcare professional.

Keep this leaflet with the medicine.
You may need to read it again.

What NovoThirteen® is used for

NovoThirteen® contains the active substance catridecacog, which is identical to human coagulation factor XIII, and is produced by recombinant technology. FXIII is an enzyme necessary for blood clotting.

NovoThirteen® is used to prevent bleeding in patients who are missing the factor XIII (A-subunit) protein. NovoThirteen® replaces the missing Factor XIII and helps to stabilise the initial blood clot by producing a mesh around the clot.

Ask your doctor or healthcare professional if you have any questions about why NovoThirteen® has been given to you.
Your doctor may have prescribed it for another reason.

Before you use NovoThirteen®

When NovoThirteen® should not be used

You should not use or be treated with NovoThirteen® if you have an allergy to:

- catridecacog or any of the ingredients listed at the end of this leaflet

(refer to the section "Side effects" to look for signs of an allergic reaction).

If you are uncertain as to whether you have such an allergy, raise this concern with your doctor.

Do not use it after the expiry date ('Expiry') printed on the carton and label.

Do not use NovoThirteen® if the packaging is torn, shows signs of tampering or does not look quite right.

Before you start to use it

Tell your doctor if you:

- have, or have ever had, a higher risk of blood clots forming (thrombosis), as NovoThirteen may increase the severity of a pre-existing blood clot;
- are allergic to rFXIII, yeast protein or to any of the ingredients in NovoThirteen®;
- are using other blood clotting factors. It is not recommended to use NovoThirteen® and recombinant factor VIIa (another blood clotting factor) together;
- are pregnant or trying to become pregnant;
- are breast-feeding or planning to breast-feed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- blood clots (thrombosis);
- liver disease or liver damage

Contact your doctor immediately:

- If you experience unexpected bleeding during your treatment with NovoThirteen®. Your doctor will prescribe an alternative treatment to treat the bleeding.

Antibodies with neutralising effect against NovoThirteen® could decrease the effectiveness of the treatment and thereby result in unexpected spontaneous bleeding episodes. Neutralising antibodies have not been seen in clinical trials with NovoThirteen®.

Tell your doctor if you plan to have surgery.

If you have not told your doctor/s about any of the above, tell him/them before you use NovoThirteen®.

Taking other medicines

Do not use NovoThirteen® and blood clotting factor concentrates at the same time.

Tell your doctor before you use NovoThirteen® and medicines used to reduce the dissolving of blood clots.

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

Immediately before you use it

Make sure that:

- the packaging is not damaged or torn;
- the protective tamper-proof plastic caps are in place, and are not loose or missing;
- the NovoThirteen® powder in the vial is white and the solvent is a clear colourless solution;
- the vials are not damaged

Using NovoThirteen®

How to use NovoThirteen®

Start of treatment with NovoThirteen® should be supervised by a doctor with experience in rare bleeding conditions. Following treatment cycles should also be supervised by a doctor for a period of time. Always use this medicine exactly as your doctor has told you. Check with your doctor or healthcare professional if you are not sure.

NovoThirteen® is given as an injection into a vein. Solvent must be added (reconstitution) to the vial of NovoThirteen® powder before the solution is injected. The solution should be clear and colourless.

Reconstitution and injection:
Please refer to the user instructions.

NovoThirteen® is for single use in one person only. Once NovoThirteen® has been prepared for injection, it should be used immediately. Discard your vial after use.

If the reconstituted product is not used immediately it should be used within 3 hours if stored at temperatures below 25°C or within 24 hours if stored at 2 - 8°C. If it is left longer, the medicine may no longer be sterile and the amount of activated rFXIII will increase. Activated rFXIII may increase the risk of getting a blood clot (thrombosis).

Once NovoThirteen® has been reconstituted it must not be frozen. If the reconstituted product does freeze it must not be used and must be discarded.

When and how much to use

NovoThirteen® is given as an injection into a vein. Your dose will depend on your body weight. The usual dose is 35 IU for each kilogram of body weight. The injections are given once a month (every 28 +/- 2 days).

Based on the concentration of NovoThirteen® solution, the dose volume to be injected (in millilitres) can be calculated from this formula:

Dose volume in millilitres = 0.042 x your body weight in kg.

Use in small children
If you need to give NovoThirteen® to a child weighing less than 24 kg you should dilute the reconstituted NovoThirteen® with 6.0 mL of sodium chloride 0.9% solution for injection. This makes the dosing of small children easier. For more information see section **'Dilution of the reconstituted product with sodium chloride 0.9% solution for injection'** in the NovoThirteen® user instruction.

The dose volume **for the use in small children** can be calculated from this formula

Dose volume in mL = 0.117 x body weight in kilograms.

Your doctor may adapt the dose if this is deemed necessary.

The reconstituted NovoThirteen® should be administered as a slow bolus intravenous injection at a rate not higher than 2 mL/minute.

For more information on how to get your injection ready, see 'NovoThirteen® User Instructions'.

For more information about how to inject NovoThirteen® contact your doctor

After you use it

- Do not refill NovoThirteen® vials.
- Healthcare professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of needle stick injury.

How long to use it

Do not stop using NovoThirteen® without consulting your doctor.
Your doctor will explain what might happen if you stop treatment and discuss other options with you.

If you use too much (overdose)

If you are given or if you give yourself too much NovoThirteen® you should contact your doctor immediately. Your doctor will take appropriate action.

If you have any concerns about taking this medicine, ask your doctor or haemophilia nurse.

If you forget to use it

You should contact your doctor who will take the appropriate action. Do not take a double dose to make up for a forgotten dose.

While you are using NovoThirteen®

Things you must do

You and your doctor should monitor your bleeding. **Tell your doctor or nurse if your bleeding gets worse.**

Contact your doctor immediately:

- If you experience unexpected bleeding during your treatment with NovoThirteen®. Your doctor may prescribe an alternative treatment to treat the bleeding.
- If you experience unexpected spontaneous bleeding during treatment with Factor XIII containing products. Antibodies against NovoThirteen® could decrease the effectiveness of the treatment and thereby result in unexpected spontaneous bleeding episodes. **Contact your doctor immediately if bleeding occurs.**

Things you must not do

Do not give NovoThirteen® to anyone else, even if they have the same condition as you.

Do not use NovoThirteen® to treat any other complaints.

Do not stop using NovoThirteen®, or adjust the dosage, without checking with your doctor.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort
- pain in the legs or arms
- frequent infections, such as fever, severe chills, sore throat or mouth ulcers which may be symptoms of a lack of white blood cells

The above list includes the more common side effects of your medicine.

Contact your doctor immediately, or go to the accident and emergency department at your nearest hospital if you have an allergic reaction. The signs might include:

- sudden signs of allergy, such as rash, hives or itching, swelling of the face, lips, tongue or other parts of the body
- pinkish, itchy swellings on the skin
- shortness of breath, wheezing or difficulty breathing
- low blood pressure (cold clammy skin, rapid weak heartbeat)
- feeling dizzy and sweating

These are serious side effects and you may need urgent medical attention.

Your doctor will have more information about unwanted effects of NovoThirteen®.

Tell your doctor or haemophilia nurse as soon as possible if you notice any side effects or do not feel well while you are using NovoThirteen®.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Ask your doctor or haemophilia nurse to answer any questions you have.

Storage

NovoThirteen® must be stored at 2-8ºC. It should not be frozen. If the product freezes it should be discarded. NovoThirteen® must only be used if the package is undamaged and the use by ('expiry') date marked on the pack has not passed.

Protect from light.

Never use NovoThirteen® after the expiry date printed on the label and carton.
The expiry date refers to the last day of that month.

Never use NovoThirteen® vials if the solution is not clear and colourless when reconstituted with the solvent.

Keep out of the reach of children.

Product Description

NovoThirteen® can only be obtained from a hospital or haemophilia treatment centre.

This leaflet does not tell you all that is known about NovoThirteen®. **If you have any questions about NovoThirteen®, ask your doctor or nurse.**

What it looks like

NovoThirteen® is supplied as a white powder, in a glass vial. The powder must be dissolved with the solvent before it is used.

Ingredients

The active ingredient in NovoThirteen® is recombinant coagulation factor XIII (rFXIII), which is also called catridecacog (rys). NovoThirteen® is made by genetic engineering.

Each vial contains 2500 IU (International Units) (15.0 mg) of rFXIII. Each vial also contains sodium chloride, sucrose, polysorbate 20 and L-histidine.

Sodium hydroxide and hydrochloric acid are used to adjust the pH.

The solvent vial contains water for injections. After reconstitution, 1 mL of the solution contains 833 IU catridecacog (activated).

Manufacturer

NovoThirteen® is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.
Level 321 Solent Circuit
Baulkham Hills NSW 2153

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Australian Registration Numbers: AUST R 201776

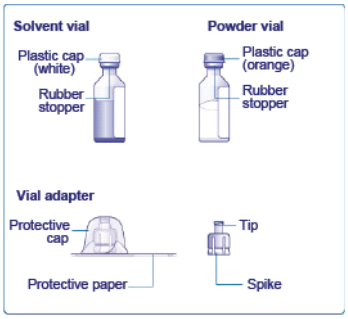
NovoThirteen® is a registered trademark of Novo Nordisk HealthCare AG, Switzerland.

NovoCare® is a registered trademark of Novo Nordisk A/S.

For further information call the NovoCare® Customer Care Centre on 1800 668 626 (Australia).

www.novonordisk.com.au

NovoThirteen® User Instructions



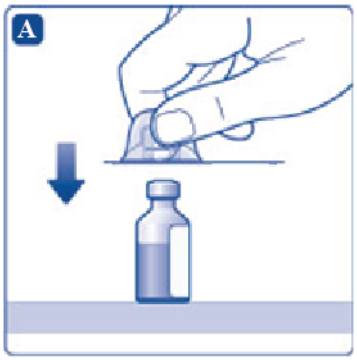
To reconstitute and administer this product the following tools are needed: a 10 ml syringe or a syringe of convenient size according to the injection volume, alcohol swabs, the included vial adaptor and an infusion set (tubing, butterfly needle).

Preparing the solution

Check the name and the colour of the package to make sure it contains the right product as well as that the product has not passed the expired date.Always use an aseptic technique. Before starting, wash your hands. Bring the powder and solvent vials to a room temperature not above 25°C, by holding them in the hands until they feel as warn as your hands. Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry before use. Do not touch the rubber stoppers after wiping them.

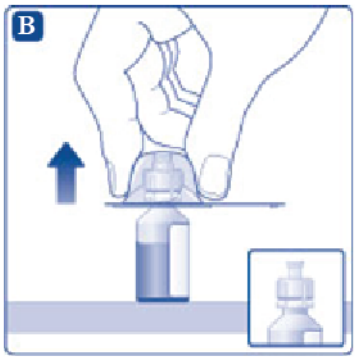
A

The product is reconstituted using the vial adaptor included.Remove the protective paper from the vial adaptor without taking the vial out of the protective cap. If the protective paper is not fully sealed, or if it is broken, do not use the vial adaptor. Place the solvent vial on a flat solid place and attach the vial adaptor to the solvent vial (water for injection). Take care not to touch the spike on the vial adaptor.



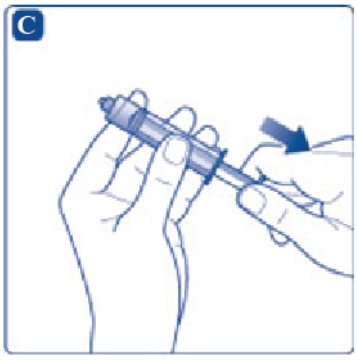
B

Once attached, remove the protective cap from the vial adaptor by lightly squeezing the protective cap with your thumb and index finger as shown.



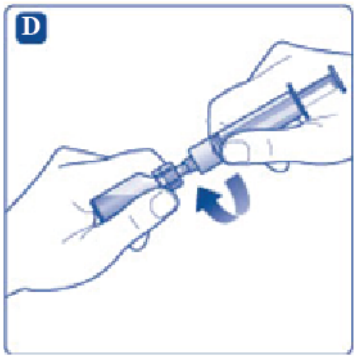
C

Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (mL equals cc on the syringe).



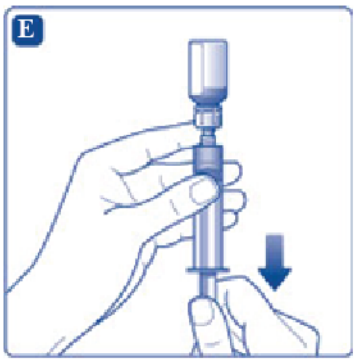
D

Screw the syringe securely onto the vial adaptor on the solvent vial. Inject air into the vial by pushing the plunger until you feel a clear resistance.



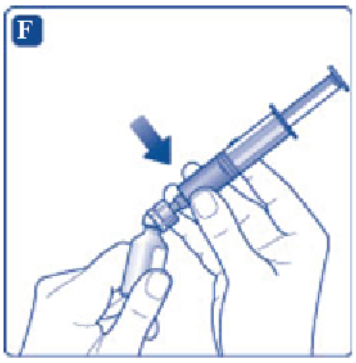
E

Hold the syringe with the solvent vial upside down. Pull the plunger to draw the solvent into the syringe.



F

Remove the empty solvent vial by tipping the syringe with the vial adaptor.



G

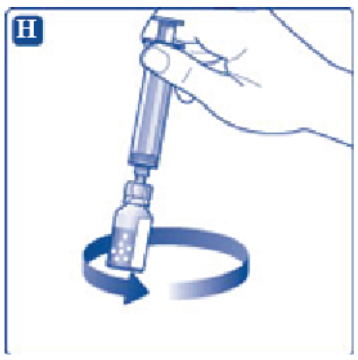
Click the vial adaptor, still attached to the syringe, onto the powder vial. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the powder as this will cause foaming.

H

Gently swirl the vial until all the powder is dissolved. Do not shake the vial as this will cause foaming.

NovoThirteen® should be inspected visually for extraneous (for any foeign) particulate matter and discolouration prior to administration. In the event of either beubg observed, discard the medicinal product.

Reconstituted NovoThirteen® is a clear, colourless solution. If a larger dose is needed, repeat the procedure in a separate syringe until the required dose is reached.



Important Information

Once prepared, NovoThirteen® for injection should be used immediately. This is because the medicine may no longer be sterile. Also the amount of non-proteolytically activated rFXIII in the medicine will increase. Non-proteolytically activated NovoThirteen® may increase the risk of getting a blood clot (thrombosis).

If the reconstituted product is not used immediately it should be used within 3 hours and can be stored at room temperature (below 25°C) during this time. Any unused product stored at room temperature for 3 hours should be discarded.If the reconstituted product is not administered immediately, it should be stored in the refrigerator at 2°C - 8°C for no longer than 24 hours.

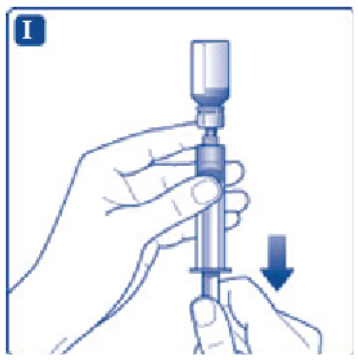
The reconstituted product must not be frozen. If the reconstituted product does become frozen it must not be used and must be discarded.

In case a dilution of the reconstituted NovoThirteen® is needed, proceed to the section 'Dilution of the reconstituted product with sodium chloride 0.9%, solution for injection'.

Injecting the solution

I

Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the vial). Hold the syringe with the vial upside down and pull the plunger to draw up the amount calculated for the injection.

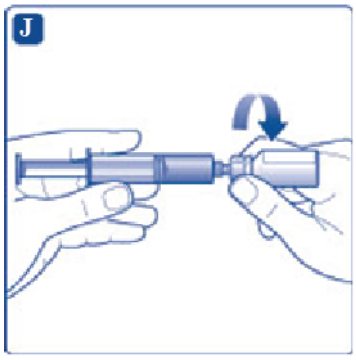


J

Unscrew the vial adaptor with the vial. The product is now ready for injection in the vein. Follow the injection procedure as instructed by your healthcare professional.

Following reconstitution the product should be administered separately and not mixed with infusion solutions nor be given in a drip.

The preparation should be administered as a slow bolus intravenous injection at a rate not higher than 2 mL/minute.



K

Safely dispose of the syringe, vial adaptor, infusion set and vials. Any unused medicinal product or waste material should be disposed of in accordance with local requirements or as instructed by your healthcare professional.

Dilution of the reconstituted product with sodium chloride 0.9%

If dilution of the reconstituted NovoThirteen® is necessary in order to be able to handle the dosing of children below 24 kg the reconstituted NovoThirteen® should be diluted with 6.0 mL 0.9% sodium chloride (see section 'Using NovoThirteen® - Use in small children').

User instruction on how to dilute the reconstituted NovoThirteen®

To dilute the reconstituted NovoThirteen® the following tools are needed: a vial containing sodiuk chloride 0.9% solution for injection, a 10 mL syringe, alcohol swabs.

General instruction for dilution

The dilution should be performed in accordance with aseptic rules.

Carefully draw 6.0 mL sodium chloride 0.9%, solution for injection, into the 10 mL syringe.

Slowly inject the 6.0 mL sodium chloride 0.9%, solution for injection, into the reconstituted NovoThirteen® vial.

Gently swirl to mix the solution.

The diluted solution is a clear, colourless solution. Check the injection solution for particulate matter and for discolouration. If either is noticed, please discard.

Ask your doctor for advice before the reconstituted NovoThirteen® is diluted with sodium chloride 0.9%, solution for injection.