

Package leaflet: Information for the user

NovoThirteen 2500 IU powder and solvent for solution for injection

catridecacog (recombinant coagulation factor XIII)

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What NovoThirteen is and what it is used for
2. What you need to know before you use NovoThirteen
3. How to use NovoThirteen
4. Possible side effects
5. How to store NovoThirteen
6. Contents of the pack and other information.

1. What NovoThirteen is and what it is used for

What NovoThirteen is

NovoThirteen contains the active substance catridecacog, which is identical to human coagulation factor XIII, an enzyme necessary for blood clotting. NovoThirteen replaces the missing factor XIII and helps to stabilise the initial blood clot by producing a mesh around the clot.

What NovoThirteen is used for

NovoThirteen is used to prevent bleeding in patients who do not have enough or are missing part of factor XIII (that is called A-subunit).

2. What you need to know before you use NovoThirteen

It is important that you use NovoThirteen for injection immediately after preparation.

Do not use NovoThirteen

- If you are allergic to catridecacog or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, ask your doctor before using this medicine.

Warnings and precautions

Talk to your doctor before using NovoThirteen:

- 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.
- If you have or have ever had liver damage.

Contact your doctor immediately:

- If you experience bleeding during your treatment with NovoThirteen occurring spontaneously and/or requiring treatment.

- If you experience an allergic reaction to NovoThirteen. The signs may include: hives, itching, swelling, difficulty breathing, low blood pressure (signs include paleness and coldness of skin, rapid heartbeat), feeling dizzy and sweating.

Other medicines and NovoThirteen

Tell your doctor if you are using, have recently used or might use any other medicines.

It is not recommended to use NovoThirteen and recombinant coagulation factor VIIa (another blood clotting factor) together.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or if you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

NovoThirteen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per injection, i.e. essentially 'sodium-free'.

3. How to use NovoThirteen

Your treatment with NovoThirteen should be initiated by a doctor experienced in the treatment of rare bleeding disorders.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Before you can use NovoThirteen for injection you need to reconstitute the product. Please see NovoThirteen user instructions.

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

If you experience a bleed, you should contact your doctor who will decide if an injection is needed. NovoThirteen should be injected at a rate not higher than 2 ml/minute.

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 = $0.042 \times$ your body weight in kilograms.

You should only use the prescribed dose calculated by your doctor from this formula considering that the usual dose and the concentration of NovoThirteen are different from those of the other products which contain factor XIII.

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

Use in small children

For children weighing less than 24 kg the reconstituted NovoThirteen should be further diluted with 6 ml of sodium chloride 0.9%, solution for injection to be able to handle the dosing of small children. For more information see section 'NovoThirteen user instructions – Instructions of how to dilute the reconstituted NovoThirteen'.

The dose volume for the reconstituted NovoThirteen diluted with 6 ml sodium chloride 0.9%, solution for injection can be calculated from this formula:

Dose volume in millilitres = $0.117 \times$ body weight in kilograms.

Use in children and adolescents (weighing more than 24 kg)

NovoThirteen can be used in children and adolescents in the same way as in adults for both prevention of bleeds and if you experience a bleed.

If you use more NovoThirteen than you should

There is limited information on overdose with NovoThirteen. None of the reported cases have shown any signs of illness. Contact your doctor if you have injected more NovoThirteen than you have been instructed.

If you forget to use NovoThirteen

If you forget an injection of NovoThirteen, talk to your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop using NovoThirteen

If you stop using NovoThirteen, you are not protected against bleeding. Do not stop using NovoThirteen without talking to your doctor. Your doctor will explain what might happen if you stop treatment and discuss other options with you.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects include:

Common (may affect up to 1 in 10 people):

- Headache (most common side effect)
- Pain where the injection is given
- Pain in the legs and arms
- Increased amount of small protein fragments caused by break down of blood clots
- A drop in the number of some types of white blood cells. This means your body may be more prone to infections
- Development of antibodies against factor XIII which have no influence on the effect of the drug.

Side effects in children:

The side effects observed in children are the same as also observed in adults but the side effects may be more common in children than in adults.

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 .

Great Britain

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 NovoThirteen

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 the outer 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.

Store in the original package in order to protect from light.

Once prepared, NovoThirteen for injection should be used immediately.

The solution is clear and colourless. Do not use this medicine if there are particles in it or it is discoloured when reconstituted.

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 NovoThirteen contains

- The active substance is catridecacog (recombinant coagulation factor XIII: 2500 IU/3 ml, after reconstitution, corresponding to a concentration of 833 IU/ml.
- The other ingredients are for the powder sodium chloride, sucrose and polysorbate 20, L-histidine, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH adjustment) and for the solvent water for injections.

What NovoThirteen looks like and contents of the pack

NovoThirteen is supplied as a powder and solvent for solution for injection (2500 IU powder in a vial and 3.2 ml solvent in a vial, with a vial adapter).

Pack size of 1.

The powder is white and the solvent is clear and colourless.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S

Novo Allé

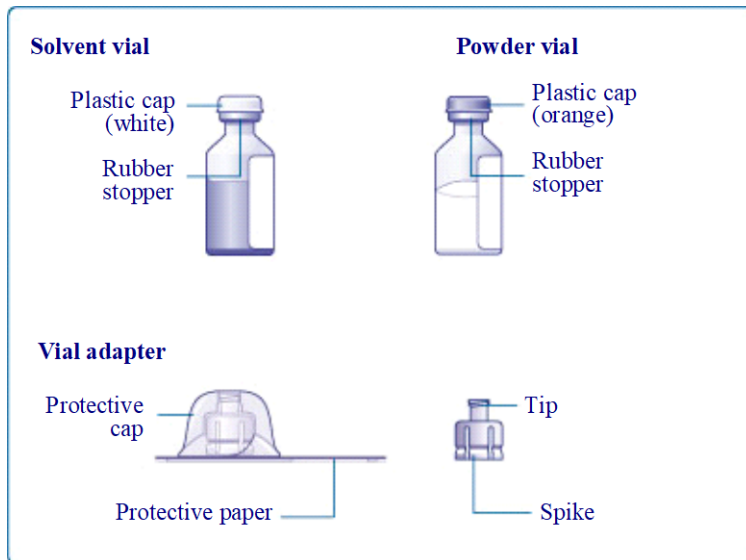
DK-2880 Bagsværd

Denmark

This leaflet was last revised in 08/2022

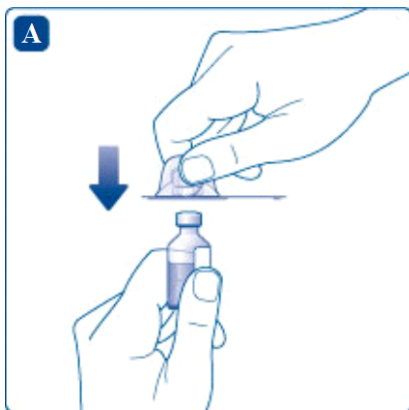
NovoThirteen user instructions

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



Preparing the solution

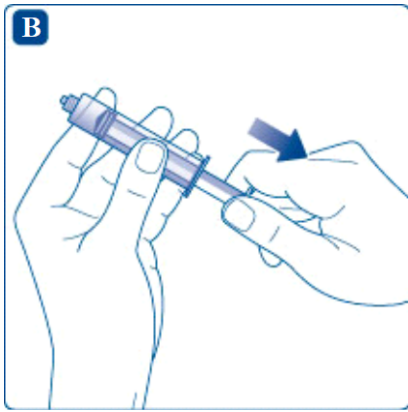
Always use an aseptic technique. Before starting, the hands should be washed. Bring the powder and solvent vials to a temperature not above 25°C, by holding them in the hands until they feel as warm as your hands. Remove the plastic caps from the 2 vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry before use.



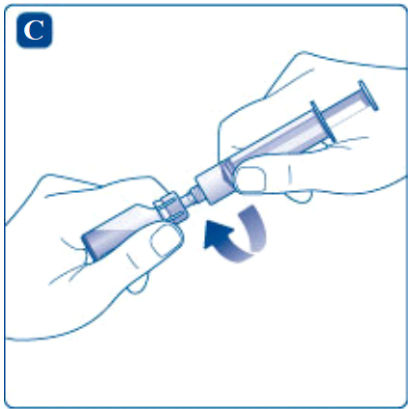
The product is reconstituted using the vial adapter included.

Remove the protective paper from the vial adapter without taking the vial adapter out of the protective cap. Attach the vial adapter to the solvent vial (water for injections). Take care not to touch the spike on the vial adapter.

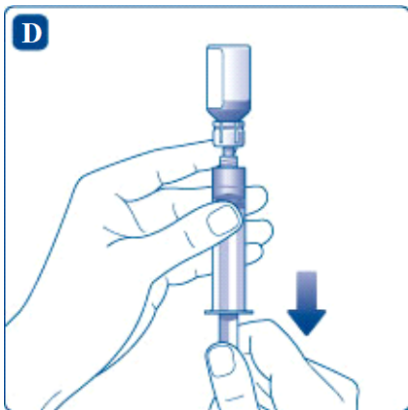
Once attached, remove the protective cap from the vial adapter.



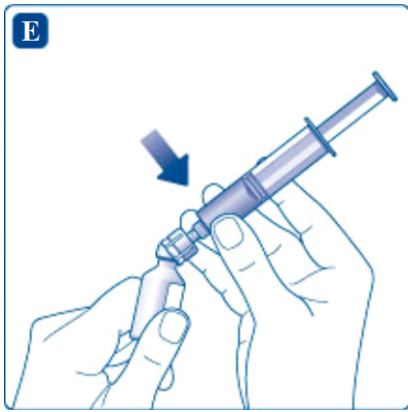
Pull the plunger to draw in a volume of air equal to the total amount of solvent in the solvent vial.



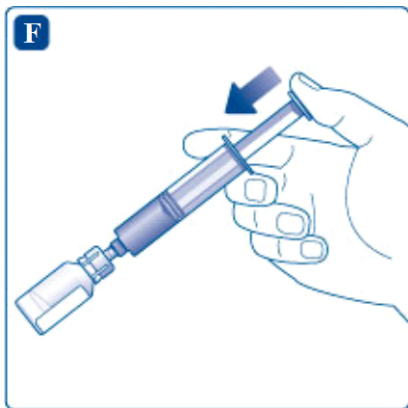
Screw the syringe tightly onto the vial adapter on the solvent vial. Inject air into the vial by pushing the plunger until you feel a clear resistance.



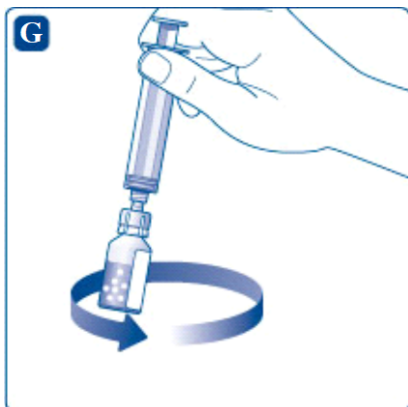
Hold the syringe with the solvent vial upside down. Pull the plunger to draw the solvent into the syringe.



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



Click the vial adapter, 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.



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 foreign) particulate matter and discoloration prior to administration. In the event of either being observed, discard the medicinal product.

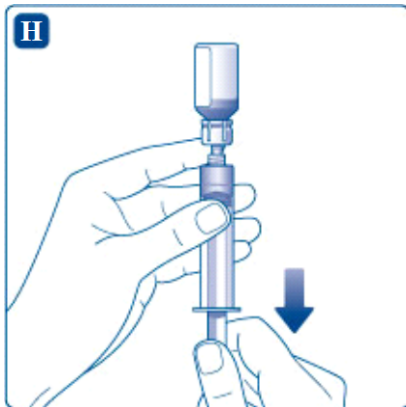
Reconstituted NovoThirteen is a clear, colourless solution.

If a larger dose is needed, repeat the procedure in a separate syringe until the required dose is reached.

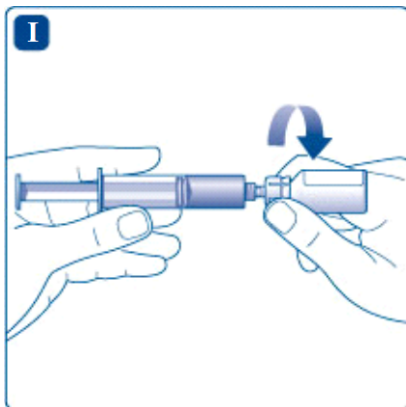
Important information

Once prepared, NovoThirteen for injection should be used immediately.

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’.



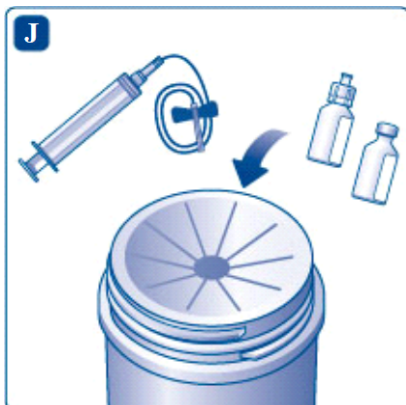
Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the vial). Hold the syringe with the vial upside down and pull the plunger to draw the amount calculated for the injection.



Unscrew the vial adapter with the vial.

The product is now ready for injection in the vein. Follow the injection procedure as instructed by your doctor.

After the injection



Safely dispose of the syringe, vial adapter, infusion set and vials. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instructions of how to dilute the reconstituted NovoThirteen

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

General instructions for dilution

The dilution should be performed in accordance with aseptic rules.

Carefully draw exactly 6 ml sodium chloride 0.9%, solution for injection, into the 10 ml syringe.

Slowly inject the 6 ml sodium chloride 0.9%, solution for injection, into the reconstituted NovoThirteen vial.

Gently swirl the vial 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.

After dilution proceed to step H.

Any residual material of the diluted product has to be discarded immediately.

In case of any questions ask your doctor or nurse.