

NovoThirteen®

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.

1. Why am I using NovoThirteen®?

NovoThirteen® contains the active substance catridecacog, which is identical to human coagulation factor XIII. NovoThirteen® is used to prevent bleeding in patients who do not have enough factor XIII.

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

2. What should I know before I use NovoThirteen®?

Do not use if you have ever had an allergic reaction to NovoThirteen® or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with NovoThirteen® 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 do I use NovoThirteen®?

- Follow your doctor's instructions, including your exact dose and dosing schedule.
- NovoThirteen® is for intravenous injection, and before use requires mixing the powder in the vial with the solvent supplied in the pack.
- More instructions can be found in Section [4. How do I use NovoThirteen®?](#) in the full CMI.

5. What should I know while using NovoThirteen® ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using NovoThirteen®.• With your doctor, monitor bleeding carefully, and notify
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	them if your bleeding gets worse.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using NovoThirteen® or change your dose without checking with your doctor. • Do not inject yourself without proper training from your doctor or haemophilia nurse.
Driving or using machines	<ul style="list-style-type: none"> • There is no specific information on the use of NovoThirteen® and driving or using machines.
Drinking alcohol	<ul style="list-style-type: none"> • There is no specific information on any possible interactions of NovoThirteen® with alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • NovoThirteen® must be stored at 2-8 °C. It should not be frozen. • Protect NovoThirteen® from light.

For more information, see Section [5. What should I know while using NovoThirteen® ?](#) in the full CMI.

6. Are there any side effects?

Contact your doctor or go to hospital if you experience symptoms of a serious allergic reaction, such as widespread skin rash, shortness of breath, wheezing, swelling of the face, lips or tongue.

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.

NovoThirteen®

Active ingredient: *catridecacog (rys)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NovoThirteen®. **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 NovoThirteen®.**

Where to find information in this leaflet:

- [1. Why am I using NovoThirteen®?](#)
- [2. What should I know before I use NovoThirteen®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NovoThirteen®?](#)
- [5. What should I know while using NovoThirteen®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NovoThirteen®?

NovoThirteen® contains the active substance catridecacog, which is identical to human coagulation factor XIII, an enzyme necessary for blood clotting.

NovoThirteen® is used to prevent bleeding in patients who do not have enough factor XIII. NovoThirteen® replaces the missing factor XIII and helps to stabilise the initial blood clot by producing a mesh around the clot.

2. What should I know before I use NovoThirteen®?

Warnings

Do not use NovoThirteen® if you:

- are allergic to catridecacog or to any of the ingredients in NovoThirteen® listed at the end of this leaflet.

Check with 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 yeast protein
- are using other blood clotting factors. It is not recommended to use NovoThirteen® and recombinant factor VIIa (another blood clotting factor) together
- have or have ever had liver damage
- plan to have surgery
- take any medicines for any other condition

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Unexpected bleeding

Contact your doctor immediately if you experience unexpected bleeding during treatment.

Antibodies with neutralising effect against NovoThirteen® could decrease the effectiveness of the treatment and result in unexpected spontaneous bleeding episodes.

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 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.

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

4. How do I use NovoThirteen®?

How much to use

- Your dose will depend on your body weight. The usual dose is 35 IU for each kilogram of body weight.
- 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 = $0.042 \times \text{your body weight in kg}$.

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® Instructions For Use.
- 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.

Do not adjust this dose or schedule without first consulting your doctor.

When to use NovoThirteen®

- The injections are given once a month (every 28 +/- 2 days).
- NovoThirteen® should be used according to your doctor's clinical assessment.

How to use NovoThirteen®

- The solvent must be added (reconstitution) to the vial of NovoThirteen® powder before the solution is injected. The solution should be clear and colourless.
- Do not inject the reconstituted medicine if the solution is **not** clear and colourless or it has anything floating in it.
- Start of treatment with NovoThirteen® should be supervised by a doctor with experience in rare bleeding conditions.
- NovoThirteen® is given as an injection into a vein (intravenously) at a rate not higher than 2 mL per minute.
- Do not inject yourself without proper training from your doctor or haemophilia nurse.

- Do not use the equipment required to inject yourself if it has been dropped or it has been damaged.

Reconstitution and injection:

- Follow the detailed instructions on how to inject NovoThirteen® in the instructions for use supplied with the product.
- These instructions are also available via the following hyperlink:
<http://medsinfo.com.au/media/noinov13>
- 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. It must not be frozen. 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).
- If it is not used in time or has been frozen, throw it away and reconstitute another vial.

After injection:

- Do not refill NovoThirteen® vials.
- Follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

If you forget to use NovoThirteen®

You should contact your doctor as soon as possible so that they may take the appropriate action.

Do not take a double dose to make up for a forgotten dose.

If you use too much NovoThirteen®

If you are given or if you give yourself too much NovoThirteen ®

You should immediately:

- contact your doctor. Your doctor will take appropriate action.

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

5. What should I know while using NovoThirteen®?

Things you should do

Continue using NovoThirteen® for as long as your doctor tells you.

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

Call your doctor straight away:

- 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.

Remind any doctor, dentist or pharmacist you visit that you are using NovoThirteen®.

Things you should not do

- Do not stop using NovoThirteen® without consulting your doctor
- Do not change the dose or schedule without consulting your doctor
- Do not give NovoThirteen® to anyone else, even if they have the same condition as you
- Do not share needles, syringes, or other injecting equipment with anyone
- Do not use NovoThirteen® to treat any other complaints.

Driving or using machines

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

There is no specific information on the use of NovoThirteen® and driving.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no specific information on any possible interactions of NovoThirteen® with alcohol.

Looking after your medicine

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

- Store it at 2 - 8 °C
- Do not freeze
- Store it in the original package to protect it from light

Keep it where young children cannot reach it.

When to discard your medicine

Do not use NovoThirteen® after the expiry date. The expiry date refers to the last day of that month.

Discard your medicine once the permitted storage time listed in "Reconstitution and injection" has passed.

Discard any solution left in the vial after you have taken the dose recommended by your doctor for your injection.

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects 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 site: <ul style="list-style-type: none">• redness• itchiness• tenderness• pain• discomfort Other: <ul style="list-style-type: none">• headache• leg or arm pain	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • frequent infections, such as fever, severe chills, sore throat or mouth ulcers which may be symptoms of a drop in the number of some types of white blood cells 	

Serious side effects

Serious side effects	What to do
<p>Severe allergic reaction:</p> <ul style="list-style-type: none"> • sudden rash, hives or itching • swelling of the face, lips, tongue or other parts of the body • shortness of breath, wheezing or difficulty breathing • low blood pressure (cold clammy skin, rapid weak heartbeat) • feeling dizzy • sweating 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

What NovoThirteen® contains

Active ingredient (main ingredient)	catridecacog (rys) 5.25 mg/mL
Other ingredients (inactive ingredients)	Powder vial <ul style="list-style-type: none">• sodium chloride• sucrose• polysorbate 20• histidine

	<ul style="list-style-type: none"> • sodium hydroxide and hydrochloric acid to adjust the pH. Solvent vial <ul style="list-style-type: none"> • Water for injections
Potential allergens	N/A

After reconstitution, 1 mL of the solution contains 833 IU catridecacog (activated).

Do not take this medicine if you are allergic to any of these ingredients.

What NovoThirteen® looks like

NovoThirteen® is supplied as a white powder, in a glass vial. The powder must be dissolved with solvent before it is used. The pack contains solvent, supplied in a glass vial and a sterile vial adaptor for reconstitution.

(AUST R 201776).

Who distributes NovoThirteen®?

NovoThirteen® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

Further information

For further information call Novo Nordisk Medical Information on 1800 668 626 (Australia).

www.novonordisk.com.au

Always check the following websites to ensure you are reading the most recent version of the NovoThirteen® Consumer Medicine Information:

- www.novonordisk.com.au
- <https://www.ebs.tga.gov.au/>

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