



Lazaro Andy Gonzalez factor XIII congenital deficiency; Florida, USA

NovoThirteen® Patient educational material

Product features, preparation, and administration
Your guide to NovoThirteen®

NovoThirteen®: recombinant therapy for congenital factor XIII A-subunit deficiency

Before using NovoThirteen®, it is important to know:

- How to safely store and handle NovoThirteen®
- How to prepare and inject NovoThirteen®
- That the usage of incorrectly stored product may increase the risk of blood clots
- The signs and symptoms of blood clots
- That the usage of NovoThirteen® for purposes other than preventing bleeding due to congenital factor XIII A-subunit deficiency may result in side effects

Table of contents

1. Using NovoThirteen®	4
2. Preparing NovoThirteen® using aseptic technique	8
3. Reconstituting NovoThirteen®	9
4. Administering NovoThirteen®	12
5. Treatment diary	18

1. Using NovoThirteen®

What your medicine is used for

You have been prescribed NovoThirteen®, a medication for the treatment of congenital factor XIII A-subunit-deficiency. NovoThirteen® replaces the missing factor XIII and helps to stabilise the initial blood clot by producing a mesh around the clot.

NovoThirteen® is used to prevent bleeding in patients with congenital factor XIII A-subunit deficiency. Use of NovoThirteen® for other purposes like treatment of breakthrough bleedings in patients with congenital factor XIII A-subunit deficiency is not part of the approved indication.

This is considered off-label use and is not approved by the Health Authority in Europe. This is because the safety and efficacy of NovoThirteen® when used in this way have not been established.

How your medicine works

Factor XIII is made up of an A-subunit that helps make a strong clot and a B-subunit that binds to the A-subunit to keep it around for a long time. An estimated 95% of people with congenital factor XIII deficiency are missing the A-subunit. Taking NovoThirteen® will restore your body's normal factor XIII activity level and help your blood clot normally. For more information about congenital factor XIII A-subunit deficiency, please read the Package Leaflet in this brochure or ask your doctor.

Where your medicine is injected

NovoThirteen® needs to be injected directly into a vein. There are two different ways that this can be done:

- Through a peripheral vein, those away from the central part of your body, such as in your arms or hands—this is called “Peripheral Venous Access” or PVA (see page 12)

- Through a central vein, those that are large and near the heart, using a medical device that your doctor inserts—this is called “Central Venous Access” or CVA (see page 15)

Your medicine should be injected immediately

NovoThirteen® should be injected immediately after it has been prepared for injection.

If appropriate, your doctor or nurse will show you how to administer your own treatment so that you can eventually do this at home. For those who are trained in self-injection, this guide is a reminder of the administration instructions you received at your clinic or treatment center on how to prepare the product for injection. If you have any questions about injecting NovoThirteen®, please talk to your doctor or nurse before trying to administer the treatment yourself.

Keeping clean (“aseptic technique”)

Because NovoThirteen® is injected directly into the bloodstream, it is very important to wash your hands before you begin preparing the injection. Also, make sure that the area where you prepare NovoThirteen® is as clean as possible.

Just like all medications, NovoThirteen® may cause side effects.

Using NovoThirteen® for purposes other than preventing bleeding due to congenital factor XIII A-subunit deficiency may also result in side effects. Be sure to talk to your doctor immediately if you believe you are experiencing any side effects.

For further information:

SFDA National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- Toll-free Number: 8002490000
- Email: npc.drug@sfd.gov.sa
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Using NovoThirteen® (cont)

Storage

Once prepared, NovoThirteen® for injection should be used immediately.

Why should you use NovoThirteen® immediately?

If you do not use NovoThirteen® immediately, the NovoThirteen® in the vial may no longer be sterile.

Also, the amount of activated NovoThirteen® in the vial will increase. Too much activated NovoThirteen® may increase your risk of getting a blood clot (thrombosis).

If NovoThirteen® has not been stored according to the described storage conditions it should not be used and be discarded.

Symptoms of a possible blood clot

Blood clots (thrombosis) can be life threatening and require immediate medical attention. If you think you have a blood clot, contact your doctor and/or call the hospital right away.

The symptoms of blood clots depend on where the clots form. The following table shows the symptoms of a blood clot based on location.

Location of clot	Symptoms
Heart	Chest pain, pain that moves down left arm, shortness of breath, sweating
Brain	Blurry vision, impaired speech, weakness, seizures
Arm or leg	Sudden pain, swelling, tenderness
Lung	Sharp chest pain, increased pulse rate, shortness of breath, fever, coughing up blood, sweating
Stomach	Stomach pain, vomiting, diarrhoea

Using NovoThirteen® (cont) Injecting at home

If appropriate, your doctor or nurse will train you so that you can eventually prepare and inject this medicine by yourself at home. For those who are trained, this guide can be used as a reminder of the instructions you were given at your clinic or treatment centre. If you have any questions, please talk to your doctor or nurse before doing this at home.

Use in small children

If your child is less than 24 kg your treatment center will support you in the process of preparing and diluting the product for injection. Please refer to the section on page 10 "Use in small children -Dilution of the reconstituted product with sodium chloride 0.9%, solution for injection" and follow the instructions given by your doctor.

Collect together everything you need

Check to make sure you have all the necessary equipment. NovoThirteen® comes with a vial adapter but no syringes or Infusion Kit. You or your doctor will need to supply these items.

You should only reconstitute NovoThirteen® if you are able to inject it immediately afterwards.

Full list of items that you need

- a. Powder vial (Containing NovoThirteen[®])
- b. Solvent vial (Containing water for injections)
- c. Vial adapter
- d. Syringe
- e. Alcohol swabs
- f. Butterfly needles—at least 2
- g. Tape
- h. Gauze or cotton ball
- i. Tourniquet

2. Preparing NovoThirteen[®] using aseptic technique

Washing your hands

- Wash your hands with soap and running water. Dry them well with a clean towel, and make sure that the area where you are preparing the injection is as clean as possible

Preparing the vials

- Bring both vials to room temperature (15° to 25° Celsius). You can do this by holding them in your hands for about a minute. The temperature of the vials must not go above 37° Celsius once they have been mixed together
- Remove the plastic caps from the 2 vials (one with the powder and one with the solvent for reconstitution). 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

3. Reconstituting NovoThirteen[®] Using the vial adapter

- The product can be reconstituted using the included vial adapter
- Remove the protective paper from the vial adapter but do not unscrew the protective cap
- Attach the vial adapter to the solvent vial
- Do not touch the spike on the vial adapter
- Once attached, remove the protective cap from the vial adapter

Drawing up air

- Pull the plunger to draw in 3.2 ml of air. This is equal to the amount of solvent in the solvent vial (3.2 ml)
- 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

Drawing up the solvent

- Hold the syringe with the solvent vial upside down. Pull the syringe plunger out to draw all the solvent into the syringe
- Remove the empty solvent vial by tipping the syringe. Keep the vial adapter attached to the syringe

Adding the solvent to the powder

- Click the vial adapter, still attached to the syringe, onto the powder vial
- Hold the syringe slightly tilted with the vial facing downward
- Push the plunger slowly to inject the water for injection into the vial
- Make sure to aim the stream of water at the inside wall of the vial. Do not aim directly at the NovoThirteen[®] powder—this may cause foaming

Reconstitution

- While holding the syringe, gently swirl the vial until all the powder is dissolved. Do not shake the vial—this may cause foaming
- Do not use it if there are any bits inside or it is the wrong colour. The medicine should be clear and colourless when fully reconstituted
- If you have been prescribed a dose that is more than 1 vial, you will need to mix up more medicine before injecting. Mix up the rest of the medicine in separate syringes until you have enough for your required dose
- Once prepared, NovoThirteen® for injection should be used immediately. Use in small children. Dilution of the reconstituted product with sodium chloride 0.9%,

solution for injection

If NovoThirteen® is injected into a child weighing less than 24 kg the reconstituted NovoThirteen® should be diluted with 6.0 ml of sodium chloride 0.9%, solution for injection to be able to handle the dosing of small children.

The dose volume after dilution with 6 ml of sodium chloride 0.9%, solution for injection can be calculated by using the below formula.

Dose volume of diluted NovoThirteen® in ml = $0.117 \times \text{subject body weight in kilograms}$.

*The calculation of the correction factor 0.117 is related to the exact quantity of the product and not the nominal value of the product.

User instruction 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 6.0 ml sodium chloride 0.9%, solution for injection, into the 10ml syringe
- Slowly inject the 6.0 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. Any residual material of the diluted product has to be discarded immediately. In case of any question ask your doctor. The below table includes a calculation of the injection volume (ml) of NovoThirteen® diluted with 6 ml of sodium chloride 0.9%, solution for injection, compared to a body weight interval (kg) for children having body weight below 24 kg.

Body weight interval (kg)	Injection volume of diluted product (ml)
1,7 - 2,5	0,20
2,6 - 3,3	0,30
3,4 - 4,2	0,40
4,3 - 5,0	0,50
5,1 - 5,9	0,60
6,0 - 6,7	0,70
6,8 - 7,6	0,80
7,7 - 8,4	0,90
8,5 - 9,3	1,0
9,4 - 10,2	1,10
10,3 - 11,0	1,20
11,1 - 11,9	1,30
12,0 - 12,7	1,40
12,8 - 13,6	1,50
13,7 - 14,4	1,60
14,5 - 15,3	1,70
15,4 - 16,1	1,80
16,2 - 17,0	1,90
17,1 - 17,8	2,00
17,9 - 18,7	2,10
18,8 - 19,6	2,20
19,7 - 20,4	2,30
20,5 - 21,3	2,40
21,4 - 22,1	2,50
22,2 - 23,0	2,60
23,1 - 23,8	2,70
23,9 - 24,7	2,80

Drawing up your medicine

- Just before the injection, make sure 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 required for the injection
- Unscrew the vial adapter with the vial from the syringe
- Your medicine is now ready to inject. Use it immediately

4. Administering NovoThirteen®

Home injection of NovoThirteen® using peripheral venous access (PVA)

PVA involves injecting medication into the peripheral veins. Peripheral veins are veins away from the central part of your body, such as veins in your arms or hands.

Washing your hands

- Wash your hands with soap and running water. Dry them well with a clean towel

Cleaning your injection site

- Clean the skin with alcohol using an alcohol swab and allow it to dry. It is important to clean the skin to stop germs from entering the vein.

Using the tourniquet to help insert the

butterfly needle

- Apply a tourniquet above the site you want to use 
- After applying the tourniquet, flex your hand or wrist for a short time to help make the veins easier to see and feel
- Hold onto the wings of the butterfly needle with the bevel facing up 
- Insert the needle at a 20-to 30-degree angle. You may feel a pop and see a flash of blood in the tubing, this means that the butterfly needle is now inside the vein 
- Level the needle until it is flat against the surface of the skin
- Apply a piece of tape over the butterfly wings to secure the needle in place
- Check that the needle is in the correct position by gently pulling back on the syringe plunger. If you notice blood in the tubing while doing so, you are ready to begin the injection

Only inject the amount that your doctor told you to inject. This may be only part of a vial. This is normal. Injecting more than you are supposed to use or using a whole vial when it was not prescribed could lead to side effects.

Injecting

- Remove the tourniquet
- Start to inject NovoThirteen® by gently pushing down on the syringe plunger. You should inject at the rate described on the package insert. Use a smooth, steady pressure



- Check for puffiness in the area. This may indicate that you have gone all the way through the vein

Removing the butterfly needle

- Remove the butterfly needle once all of the NovoThirteen® has been injected. Apply pressure over the area with dry gauze or a cotton ball for at least 5 minutes

After your injection

- Safely dispose of the syringe, vial adapter, injection set, and vials. Any unused product or waste material should be disposed of according to local laws
- Clean your work area, wash your hands again, and record the treatment in your treatment diary



Note: Please adapt administration instructions accordingly to local legal guidance.

Administering NovoThirteen® (cont) Helpful hints

- Keeping your body temperature warm is important. Take a warm shower before the injection to help make veins larger and easier to access
- Avoid reconstituting NovoThirteen® unless you are ready to inject it immediately
- Try to inject into straighter parts of the vein rather than curved parts
- Avoid injecting into bumps in the vein
- Use different injection sites to avoid scarring
- If you think you have missed a vein and injected into the tissue, seek advice from your doctor. Your doctor may measure the amount of fac-

tor XIII in your system to calculate the amount you should redose

- Any local reaction at the injection site, such as redness, swelling, pain, warmth, or discolouration, should be reported to your doctor

Injecting NovoThirteen® using central venous access (CVA)

CVA refers to injecting factor and other medications using large veins near the heart. CVA devices (CVADs) are medical devices inserted by a doctor. CVADs allow factor and other medications to be delivered into one of these large veins.

If you have CVA, your doctor can administer NovoThirteen®. If you have proper training, your doctor may train you so that you could also administer NovoThirteen® by yourself through the cannula. The cannula must be flushed with 5 ml of normal saline both before and after administration of the drug.

NovoThirteen®

3500 IU (15 ml)

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.

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.

What NovoThirteen® is used for
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 you need to know before you 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.
- If you are allergic to recombinant blood coagulation factor XIII (see section 4. Possible side effects for signs of hypersensitivity/allergy).

Contact your doctor immediately:

- If you experience unexpected bleeding during your treatment with NovoThirteen®, your doctor will prescribe an alternative medicine to treat the bleeding.
- FVIII antibodies with neutralising effect against NovoThirteen® (these are antibodies that block the factor XIII you are using) 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®.

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

The use of NovoThirteen® may be necessary during pregnancy and breast-feeding.

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

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.

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 to 32 days).

The dose volume to be injected (in millilitres) can be calculated from this formula:

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

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

Dilution of the reconstituted product with 0.9% sodium chloride.

If NovoThirteen® is injected into a child weighing less than 24 kg the reconstituted NovoThirteen® should be diluted with 6.0 ml of 0.9% sodium chloride to be able to handle the dosing of small children. For more information see section NovoThirteen® User Instructions - Dilution of the reconstituted product with 0.9% sodium chloride.

The dose volume can be calculated by using the below formula: Dose volume in ml = 0.17 × body weight in kilograms.

The reconstituted NovoThirteen® should be injected at a rate not higher than 2 ml/minute.

For more information on how to give your injection, read, see NovoThirteen® User Instructions.

Use in children and adolescents

NovoThirteen® can be used in children and adolescents in the same way as in adults.

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.

Allergic reactions

If you have an allergic reaction, see a doctor straight away.

The signs may include:

- Hives, itching
- Swelling
- Difficulty in breathing
- Low blood pressure (paleness and coldness of skin, rapid heartbeat)
- Feeling dizzy and sweating.

Other 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 dots
- A drop in the number of some types of white blood cells. This means your body may be more prone to infections
- Development of non-neutralising factor XIII antibodies which have no influence on the effect of the active substance.

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.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

The National Medicines Commission and Drug Safety Centre (BfCI):
• Tel: +49 69 95661-12057662
• Call NMC at +49 611-2038222
• Fax: +49 611-2038223
• E-mail: nmc@bfi.de
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• Tel: +49 69 95661-12057662
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• Fax: +49 611-2038223
• E-mail: nmc@bfi.de
• Web: www.bfi.de

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. 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. If the reconstituted product is not used immediately it should be used within 3 hours if stored at temperature below 25°C or within 24 hours if stored at 2°C - 8°C. This is because if it is left longer, the medicine may no longer be sterile and NovoThirteen® will become activated. Activated NovoThirteen® may increase the severity of a pre-existing blood clot.

Any unused product stored below 25°C for more than 3 hours or at 2°C - 8°C for more than 24 hours should be discarded.

The solution is clear and colourless. Do not use this medicine if there are particles in it or if 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) 3500 IU/15 ml, after reconstitution, corresponding to a concentration of 833 IU/ml.

The other ingredients are: the powder sodium chloride, sucrose and poloxamer 20, L-histidine, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and for the solvent water for injections.

*Produced in yeast (cell Saccharomyces cerevisiae) by recombinant DNA technology.

What NovoThirteen® looks like and contents of the pack
NovoThirteen® is supplied as a powder and solvent for solution for injection (3500 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 Søgaard, Denmark
Leaflet revised date: June 2015

NovoThirteen®

3500 IU (15 ml)

Powder and solvent for solution for injection
catridecacog (recombinant coagulation factor XIII)

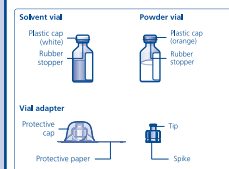
8/05/24/06-01

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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, wash your hands. Bring the powder and solvent vial 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 vial. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry before use.

1. The product is reconstituted using the vial adapter

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.

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

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

3. 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.

4. 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.

5. 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 label 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. This is because if left, the medicine may no longer be sterile. Also, the amount of activated NovoThirteen® in the medicine will increase. 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 of reconstitution and can be stored at room temperature during this period.

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.

In case of dilution of the reconstituted NovoThirteen® is needed proceed to the section Dilution of the reconstituted product with 0.9% sodium chloride.

Injecting the solution

Ensure that the plunger is pushed all the way in and the solution is drawn up into the syringe. Turn 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.

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 healthcare professional.

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.

Dilution of the reconstituted product with 0.9% sodium chloride

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 3. How to use NovoThirteen® - Use in small children).

To dilute the reconstituted NovoThirteen® the following tools are needed: a vial containing 0.9% sodium chloride, a 10 ml syringe or a syringe of a convenient size according to injection volume, alcohol swabs and a vial adapter.

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

If the reconstituted NovoThirteen® is diluted with 0.9% sodium chloride proceed to step H injecting the solution.

5. Treatment diary

Make sure to record the following data after each injection:

- Date of injection
- Next injection
- Notes

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In case you had any side effects related to the drug use, please contact:

SFDA National Pharmacovigilance and Drug Safety Center (NPC):

- Fax: +966-11-205-7662
- Toll-free Number: 8002490000
- Email: npc.drug@sfd.gov.sa
- online: <http://ade.sfd.gov.sa/>

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