

XYNTHA®

morotocog alfa rch, also known as recombinant coagulation factor VIII

Consumer Medicine Information

What is in this leaflet

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

If you have any concerns about using XYNTHA, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with your XYNTHA. You may need to read it again.

What XYNTHA is

XYNTHA is a protein called coagulation factor VIII protein product that is important for helping your blood clot. XYNTHA is produced by recombinant DNA technology and is made in a laboratory, rather than isolated from human blood donors, which is where plasma derived factor VIII comes from. Mammalian cells, which have the DNA for human coagulation factor VIII put in them, are grown in large amounts in cell culture laboratories. These cells make recombinant human factor VIII, which is released into cell culture media and then very highly purified. XYNTHA does not contain any human blood or preservatives and no animal or human-derived materials have been used in the cell culture process, purification or final formulation of XYNTHA.

What XYNTHA is used for

People with haemophilia A (congenital factor VIII deficiency or classic haemophilia) do not have enough coagulation factor VIII. XYNTHA works by replacing factor VIII to enable blood to clot.

XYNTHA is used for the control and treatment of bleeding and the routine and surgical prevention of bleeding in people with haemophilia A.

XYNTHA does not contain von Willebrand factor and so is not used to treat von Willebrand's disease

XYNTHA has been approved for use in haemophilia A. Ask your doctor if you have any questions about why XYNTHA has been prescribed for you.

There is no evidence that XYNTHA is addictive.

XYNTHA is not expected to affect your ability to drive a car or operate machinery.

Before you use XYNTHA

When you must not use it

Do not use XYNTHA if you know you are allergic to morotocog alfa, hamster proteins or any of the ingredients of XYNTHA.

Signs of allergy include a skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, difficulty breathing, shortness of breath and/or a swollen face.

Your doctor will not prescribe XYNTHA if you have von Willebrand's disease.

XYNTHA does not contain von Willebrand's factor.

Do not use XYNTHA after the expiry date (Exp) printed on the pack.

Do not use XYNTHA if the packaging is torn or shows signs of tampering.

Before you start to use it

Certain people must use XYNTHA with caution. Ask your doctor for advice.

You must tell your doctor if:

- You are pregnant or planning to become pregnant.
It is not known whether XYNTHA can affect your ability to have children or harm your developing baby.
- You are breast feeding.
It is not known whether XYNTHA passes into breast milk.
- You are on a low salt diet.
XYNTHA contains 29 mg sodium per vial/ dual chamber syringe of reconstituted powder and this should be taken into account in a controlled sodium diet.

Your doctor will advise you whether or not to use XYNTHA or if you need to adjust the dose, or adapt your treatment.

Taking other medicines

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.

Some medicines may be affected by XYNTHA, or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Using XYNTHA

How XYNTHA is given

XYNTHA is given as an injection directly into your veins, usually by either yourself, a doctor, nurse, or other trained person.

XYNTHA is supplied as a freeze-dried powder. Before it can be injected into your vein it must be mixed with 0.9% Sodium Chloride solution. XYNTHA should be injected using the infusion set provided in the kit.

Your doctor will show you how to prepare and give an injection of XYNTHA. Once you have learned how to self-inject, you can follow the instructions for preparing and giving an injection of XYNTHA at the end of this leaflet.

Dosage

Your doctor will decide the dose of XYNTHA you will receive. The dose and duration will depend upon your individual needs for replacement factor VIII therapy.

Your doctor may decide to change the dose of XYNTHA you receive during your treatment. In the presence of an inhibitor, you may need higher doses or specific treatment. Dosage adjustment for people with kidney or liver impairment has not been studied in clinical trials.

Disposal

Dispose of all unused solution, empty vials and syringes, and used needles into a sharps container.

Medicines must not be disposed of down the toilet or via household waste. These measures help protect the environment.

Overdose

Immediately telephone your doctor or the Poisons Information Centre (in Australia; tel 13 11 26, or in New Zealand; tel 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much XYNTHA. Do this even if there are no signs of discomfort or poisoning. Always take the labelled medicine carton with you, even if it is empty.

While you are using XYNTHA

Things you must do

Contact your doctor immediately or seek emergency care if your bleeding does not stop as expected

If bleeding is not adequately controlled with the usual dose, you should be monitored in order to find out whether a factor VIII inhibitor is present. Some people receiving factor VIII products may sometimes develop antibodies or inhibitors to factor VIII, which may prevent the factor VIII product from working properly.

Stop the infusion immediately and contact your doctor, if you experience reactions such as:

Headache, fever, chills, flushing, nausea, vomiting or allergic reactions such as skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, difficulty breathing, shortness of breath and/or a swollen face.

Always follow your doctor's instructions carefully

Tell all the doctors, dentists and pharmacists who are treating you that you are using XYNTHA.

If you are about to be started on any new medicine, including medicines obtained without a prescription, tell your doctor and pharmacist that you are using XYNTHA.

If you become pregnant while you are using XYNTHA, tell your doctor.

Things you must not do

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

Do not use XYNTHA to treat any other complaints unless your doctor tells you to.

Do not stop using XYNTHA or lower the dosage, without checking with your doctor, unless you have an allergic reaction.

Side Effects

Tell your doctor immediately if you are using increasing amounts of XYNTHA in order to control a bleeding episode.

During your treatment with XYNTHA, your blood will be checked for inhibitors to factor VIII activity. Inhibitors are antibodies

against factor VIII, which are made by your immune system. The inhibitors stop the factor VIII from working as well as it used to.

Tell your doctor as soon as possible if you do not feel well while you are using XYNTHA.

Injection of any medicine intravenously may have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you experience some side effects.

Tell your doctor if you notice any of the following:

Stomach or bowel problems such as:

- nausea
- vomiting
- loss of appetite
- stomach pain or cramps
- diarrhoea.

Difficulty thinking or working because of:

- headache
- dizziness
- drowsiness
- numbness
- muscle weakness or pain
- joint pain
- excessive sweating
- flushing
- fever
- feeling faint
- chest pain
- rapid or irregular heartbeat
- chills or feeling cold.

Respiratory problems such as:

- shortness of breath
- coughing.

Changes in your sight, taste or touch such as:

- blurred vision
- altered taste

Skin problems such as:

- itching
- rash
- bruising or bleeding
- swelling of a vein from a blood clot.

Other problems such as:

- difficulties in catheter access to a vein
- injection site reaction, including pain and swelling.

These are all uncommon to very rare side effects of XYNTHA injection.

If any of the following signs of an allergic reaction happen suddenly, STOP using XYNTHA and tell your doctor immediately:

- a swollen face, lips, tongue or throat
- difficulty breathing
- shortness of breath
- chest tightness
- wheezing
- chills or feeling cold
- flushing
- dizziness
- feeling tired
- feeling restless
- nausea
- vomiting

- faintness
- rapid heartbeat
- hives
- a skin rash
- headache
- tingling
- burning and stinging at the injection site.

These can be very serious side effects. If you have them, you may have a serious allergic reaction to XYNTHA and you may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Storage

Before Reconstitution:

Keep XYNTHA in the refrigerator (2°C to 8°C). XYNTHA must be used by the expiry date on the label.

DO NOT freeze.

XYNTHA can be stored at room temperature for a single period of up to 3 months. Do not store XYNTHA above 25°C. After room temperature storage, XYNTHA can be returned to the refrigerator until the expiration date.

Do not store XYNTHA at room temperature and return it to refrigerated storage more than once.

Write the date on the package when you first store XYNTHA at room temperature.

Avoid exposure of XYNTHA to light.

Keep XYNTHA (and kit contents) where young children cannot reach it.

Do not use XYNTHA beyond the date (month and year) printed on the label after the letters 'Exp', even if it has been stored properly.

Medicines cannot be stored indefinitely.

After Reconstitution:

Use the made-up product as soon as possible after dissolving the powder.

If the made-up solution is not used right away, it should be stored at 2°C to 8°C and used within 3 hours.

Only use solutions that are clear and colourless.

Use only the accessories provided in the box for reconstitution and administration.

Product Description

What it looks like

Prefilled Dual Chamber Syringe

XYNTHA is provided in a prefilled dual chamber syringe. The top chamber contains XYNTHA powder for injection. The bottom chamber contains Sodium Chloride Solution for injection.

There are 5 strengths of XYNTHA available in the prefilled dual chamber syringe - 250 IU, 500 IU, 1000 IU, 2000 IU and 3000 IU.

The contents of the XYNTHA kit are:

- one prefilled dual chamber syringe
- one plunger rod for assembly
- one vented sterile cap
- one sterile infusion set

- two alcohol swabs
- one sticking plaster
- one sterile gauze pad

Vial and Diluent Syringe

XYNTHA is provided as a white powder for injection in a glass vial and a diluent is provided in a pre-filled syringe.

There are 4 strengths of XYNTHA - 250 IU, 500 IU, 1000 IU and 2000 IU

The contents of the XYNTHA kit are:

- one vial of moroctocog alfa powder
- one pre-filled syringe of diluent, containing 4mL sterile sodium chloride 9mg/mL (0.9%) solution for injection for reconstitution
- one sterile vial adapter reconstitution device
- one sterile infusion set
- two alcohol swabs
- one sticking plaster
- one sterile gauze pad.

Ingredients

Active ingredients: Coagulation factor VIII (moroctocog alfa (rch))

Inactive ingredients: Sucrose, calcium chloride dihydrate, L-histidine, sodium chloride and polysorbate 80.

Australian Registration Numbers

XYNTHA 250 IU prefilled dual chamber syringe: AUST R 174837

XYNTHA 500 IU prefilled dual chamber syringe: AUST R 174838

XYNTHA 1000 IU prefilled dual chamber syringe: AUST R 174839

XYNTHA 2000 IU prefilled dual chamber syringe: AUST R 174840

XYNTHA 3000 IU prefilled dual chamber syringe: AUST R 174841

XYNTHA 250 IU vial and diluent: AUST R 161714

XYNTHA 500 IU vial and diluent: AUST R 161715

XYNTHA 1000 IU vial and diluent: AUST R 161716

XYNTHA 2000 IU vial and diluent: AUST R 161717

Supplier

XYNTHA is supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348

38-42 Wharf Road
WEST RYDE NSW 2114

Toll Free Number: 1800 675 229

XYNTHA is supplied in New Zealand by:

Pfizer New Zealand Limited
PO Box 3998

Auckland
Toll Free Number: 0800 736 363

The XYNTHA administration kit is manufactured by Wyeth Farma, Algete, San Sebastian de los Reyes, Madrid, Spain.

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