

XYNTHA®

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 XYNTHA?

XYNTHA contains the active ingredient moroctocog alfa, a coagulation factor VIII product. XYNTHA is used to control and treat bleeding and prevent bleeding in people with haemophilia A. People with haemophilia A are deficient in coagulation factor VIII.

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

2. What should I know before I use XYNTHA?

Do not use XYNTHA if you have had an allergic reaction to moroctocog alfa, hamster proteins 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, are on a low salt diet, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with XYNTHA 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 XYNTHA?

- XYNTHA comes in five dosage strengths. Your doctor will decide the dosage strength and dose that you will receive.
- XYNTHA is given by injection directly into your veins. It should be injected using the infusion set provided in the pack.
- 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.
- Your doctor, nurse or pharmacist will show you how to prepare and give an injection of XYNTHA.

More instructions can be found in Section [4. How do I use XYNTHA?](#) in the full CMI.

5. What should I know while using XYNTHA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist and pharmacist you visit that you are using XYNTHA.• Contact your doctor immediately if your bleeding does not stop as expected.• Stop the infusion immediately and contact your doctor if you experience an allergic reaction.
Things you should not do	<ul style="list-style-type: none">• Do not stop using XYNTHA or lower the dose without first checking with your doctor, unless you have an allergic reaction.
Driving or using machines	<ul style="list-style-type: none">• XYNTHA is not expected to affect your ability to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store XYNTHA in the refrigerator (2°C to 8°C).

Do not freeze. Avoid exposure to light.

- XYNTHA may be stored at room temperature (below 25°C) for a single period up to 3 months. After room temperature storage it 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.
- Use the made-up solution of XYNTHA 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.

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

6. Are there any side effects?

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

XYNTHA®

Active ingredient(s): moroctocog alfa

Consumer Medicine Information (CMI)

This leaflet provides important information about using XYNTHA. **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 XYNTHA.**

Where to find information in this leaflet:

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

1. Why am I using XYNTHA?

XYNTHA contains the active ingredient moroctocog alfa, human coagulation factor VIII. Moroctocog alfa 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.

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.

2. What should I know before I use XYNTHA?

Warnings

Do not use XYNTHA if:

1. you are allergic to moroctocog alfa, hamster proteins, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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. If any of these signs occur, stop using XYNTHA and contact your doctor immediately, you may need urgent medical care.

Tell your doctor if:

- you have any other medical conditions
- you take any medicines for any other condition
- 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.

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

Tell your doctor if you are pregnant or intend to become pregnant. It is not known whether XYNTHA can affect your ability to have children or harm your developing baby.

Tell your doctor if you are breastfeeding or intend to breastfeed. It is not known whether XYNTHA passes into breast milk.

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.

Some medicines may interfere with XYNTHA and affect how 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.

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

4. How do I use XYNTHA?

How much to use

- XYNTHA comes in five dosage strengths. Your doctor will decide the dosage strength and dose of XYNTHA that 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.
- Follow the instructions provided and use XYNTHA until your doctor tells you to stop.

How to use XYNTHA

- 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, nurse or pharmacist 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 provided in the leaflet in the pack.

How to reconstitute and administer XYNTHA

- Always wash your hands before preparing and giving an injection of XYNTHA. Aseptic technique (clean and germ-free) should be used during the make-up (reconstitution) procedure.
- Use only the accessories provided in the pack for dissolving the XYNTHA powder with the sodium chloride solution and then injecting the made-up (reconstituted) XYNTHA solution.
- Inject the XYNTHA solution as soon as possible or within 3 hours after dissolving the powder.
- Only use solutions that are clear and colourless.

If you forget to use XYNTHA

XYNTHA should be used regularly as agreed with your doctor. If you miss your dose at the usual time, you should inject the next dose as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and inject your next dose when you are meant to.

Do not inject a double dose to make up for the dose you missed.

If you use too much XYNTHA

If you think that you have used too much XYNTHA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
(by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using XYNTHA?

Things you should 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, chills, flushing, rapid heartbeat, shortness of breath and/or a swollen face.

Tell all doctors, dentists and pharmacists you visit 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.

Call your doctor straight away if:

- you experience an allergic reaction
- 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.

Things you should not do

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

- 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.

Driving or using machines

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

Looking after your medicine

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

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.
- Avoid exposure of XYNTHA to light.
- XYNTHA can be stored at room temperature (below 25°C) 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.

After Reconstitution:

- Use the reconstituted (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.

Do not use this medicine after the expiry date.

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

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.

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

6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Stomach or bowel problems such as:</p> <ul style="list-style-type: none">• loss of appetite• stomach pain or cramps• diarrhoea. <p>Difficulty thinking or working because of:</p> <ul style="list-style-type: none">• drowsiness• numbness• muscle weakness or pain• joint pain• excessive sweating <p>Respiratory problems such as:</p> <ul style="list-style-type: none">• coughing <p>Changes in your sight, taste or touch such as:</p> <ul style="list-style-type: none">• blurred vision• altered taste <p>Other problems such as:</p> <ul style="list-style-type: none">• difficulties in catheter access to a vein	<p>Speak to your doctor if you have any of these side effects and they worry you.</p> <p>These are uncommon to very rare side effects of XYNTHA injection.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● injection site reaction, including pain and swelling. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● headache ● fever ● chills or feeling cold ● flushing ● nausea ● vomiting <p>Allergic reaction:</p> <ul style="list-style-type: none"> ● a swollen face, lips, tongue or throat ● difficulty breathing ● shortness of breath ● chest tightness ● wheezing ● dizziness ● feeling tired ● feeling restless ● faintness ● rapid heartbeat ● hives 	<p>Stop using XYNTHA and 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> <p>These can be very serious side effects. If you have them you may need urgent medical attention or hospitalisation. These side effects are uncommon to very rare.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● a skin rash ● tingling ● itching ● burning and stinging at the injection site. 	
<p>Heart problems such as:</p> <ul style="list-style-type: none"> ● chest pain ● rapid or irregular heartbeat <p>Skin problems such as:</p> <ul style="list-style-type: none"> ● bruising or bleeding ● swelling of a vein from a blood clot 	<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> <p>These side effects are uncommon to very rare.</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

This medicine is only available with a doctor's prescription.

What XYNTHA contains

Active ingredient (main ingredient)	moroctocog alfa
Other ingredients (inactive ingredients)	sucrose, calcium chloride dihydrate, histidine, sodium chloride and polysorbate 80.

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

What XYNTHA 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.

Each prefilled dual chamber syringe of XYNTHA is provided with a plunger rod for assembly, a vented sterile cap, a sterile infusion set, two alcohol swabs, a sticking plaster and a sterile gauze pad.

XYNTHA 250 IU: AUST R 174837

XYNTHA 500 IU: AUST R 174838

XYNTHA 1000 IU: AUST R 174839

XYNTHA 2000 IU: AUST R 174840

XYNTHA 3000 IU: AUST R 174841

Vial and Diluent Syringe

XYNTHA is provided as a white powder in a glass vial. There are 4 strengths of XYNTHA in vials - 250 IU, 500 IU, 1000 IU and 2000 IU

Each vial of XYNTHA is provided with a pre-filled diluent syringe containing 4 mL sterile sodium chloride 9 mg/mL (0.9%) solution and accessories required for making up the solution and injection. These include a sterile vial adapter reconstitution device, a sterile infusion set, two alcohol swabs, a sticking plaster and a sterile gauze pad.

XYNTHA 250 IU: AUST R 161714

XYNTHA 500 IU: AUST R 161715

XYNTHA 1000 IU: AUST R 161716

XYNTHA 2000 IU: AUST R 161717

Who distributes XYNTHA

XYNTHA is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www\(pfizermedinfo.com.au](http://www(pfizermedinfo.com.au)

XYNTHA is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 363

[www\(pfizermedinfo.co.nz](http://www(pfizermedinfo.co.nz)

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

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