

# YOUR GUIDE TO XYNTHA<sup>®</sup> DUAL CHAMBER

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INFORMATION FOR PATIENTS AND CARERS



[www.haemophilia.co.nz](http://www.haemophilia.co.nz)

**xyntha<sup>®</sup>**  
dual chamber  
Moroctocog alfa rch  
(recombinant coagulation factor VIII)

# INTRODUCTION

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This booklet aims to provide clear, practical information on the use of XYNTHA. It is designed to be kept on hand to answer common questions you may have about this treatment.

Please talk to your doctor and/or Haemophilia Treatment Centre (HTC) if you require more detailed information.

This booklet should be read in conjunction with the Consumer Medicine Information leaflet, available at [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

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# WHAT IS XYNTHA?

XYNTHA is a recombinant coagulation factor VIII product. It is used for the prevention and treatment of bleeding in adults, children and infants with haemophilia A.

## How it works.

XYNTHA works by increasing the level of factor VIII in the blood so it can clot.

## XYNTHA is a recombinant product.

Recombinant products are created in a laboratory using DNA technology.

Using the factor VIII gene, scientists can grow factor VIII in a non-human cell culture.

Factor VIII is then removed from the culture and purified using a high-tech process.

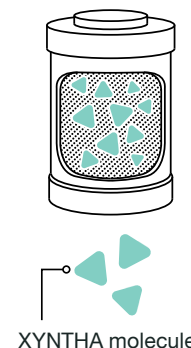
This process is designed to reduce the risk of viral contamination.

XYNTHA is made using a purification system.



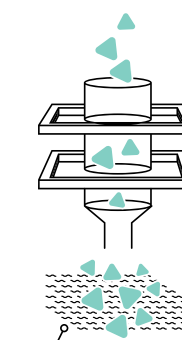
Steps in the manufacturing and purification process designed to reduce the risk of viral contamination.

Albumin-free cell culture



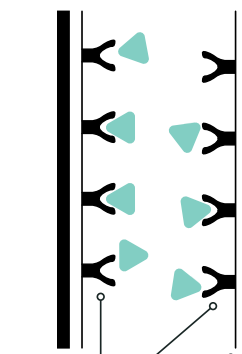
XYNTHA molecules

Initial Purification



Solvent detergent

Further Purification



Synthetic ligands

Resin wall



XYNTHA molecules

**1.** Factor VIII is grown in an albumin-free cell culture (i.e. no added human or animal material).

**2.** The solution is then purified to inactivate potential viruses.

**3.** A man-made molecule (synthetic ligand) is used to catch and hold XYNTHA so it can be collected and cleansed.

**4.** XYNTHA then goes through a tiny filter (nanofiltration) to further safeguard against potential viruses.

# THE XYNTHA DUAL CHAMBER DEVICE



## XYNTHA dual chamber is the latest innovation from Pfizer.

It's the only haemophilia device available in New Zealand that's preloaded with both factor VIII and diluent for quick and convenient treatment.

## No need for transfer, it's already done.

Available in an all-inclusive kit, the XYNTHA dual chamber syringe features an innovative all-in-one convenient design that eliminates the transfer step for ease of reconstitution. XYNTHA, ready to go when you are.

## BEFORE USING XYNTHA

### Do NOT begin treatment if:

- You are allergic to hamster proteins or any other component of XYNTHA.
- You have von Willebrand's disease. XYNTHA does not contain von Willebrand factor.
- Your XYNTHA kit is past the expiry date printed on the pack.
- Your XYNTHA packaging is torn or shows signs of tampering.

**Please read the Consumer Medicine Information leaflet before using XYNTHA.**



*Please see page 16 for possible allergic reactions*

# HOW TO USE XYNTHA?

## Your routine, your dose.

**Your treatment routine may be either:**

- **Prophylaxis:** you take XYNTHA on a regular basis so there is always factor in your system to help prevent bleeds.

**or**

- **On demand:** you take XYNTHA when you have a bleed or just before you are exposed to risk (e.g. playing sport or an active trip away).

The dose you receive is calculated especially for you and can depend on:

- How low your factor VIII levels are
- Your clinical condition
- If you have inhibitors
- Your weight
- Your response to treatment

## Recording your infusions.

Every time you use a XYNTHA pack, it's a good idea to record the name and batch number. Batch number labels on the vial can be peeled off and stuck in your diary.

However, there's now a much easier way to record your infusions. Pfizer has created a web app called TRACKER FACTORY that's especially designed for recording infusions as well as bleeds.

You can access this program by simply typing in **[www.trackerfactory.co.nz](http://www.trackerfactory.co.nz)** to any web enabled device such as your phone, iPad or desktop computer.



Apart from making it really easy to track bleeds and infusions, the data you enter is sent directly to your haemophilia nurse, so they can analyse patterns, trends or anomalies that can help to improve your care.

Other useful features include:

- Infusion schedules
- 3-D model for recording of bleeds
- Messaging capability
- Appointments diary
- Emergency button
- Emergency contacts
- Secure login system

## Staying on track.

When you or your child has haemophilia, there can be a lot to remember about the condition and treatment.

You will give yourself the best chance of treatment success by following a few simple rules:

### **Always use XYNTHA as instructed.**

Your doctor/Haemophilia Treatment Centre will have recommended a dose and treatment routine that is right for you.

### **Always have enough factor to meet your needs.**

Do regular stocktakes/rotations to be aware of how many in-date vials are left, and order more if required.

### **Stay in touch with your Haemophilia Treatment Centre.**

It is your main link to managing your condition and it is there to support you.

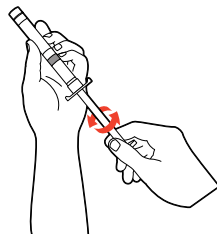
# HOW TO RECONSTITUTE XYNTHA DUAL CHAMBER

## Preparation.

- Let the XYNTHA dual chamber syringe reach room temperature.
- Wash your hands before use.
- Place the components of the kit on a clean surface.
- Throughout the reconstitution process, keep the XYNTHA dual chamber syringe upright to prevent possible leakage.
- Components should be used as soon as possible after opening.

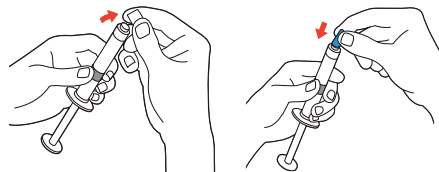
## Reconstitution Steps.

1.



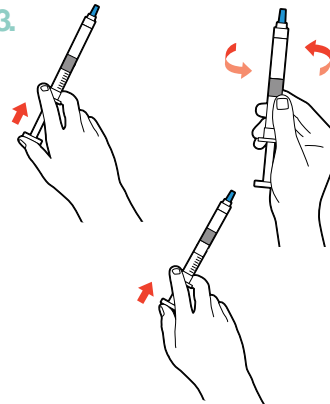
- Screw the plunger rod firmly into prefilled dual chamber syringe by pushing and turning firmly until resistance is felt.

2.



- Remove the white tamper-evident seal by bending the seal to expose the rubber tip cap.
- Remove the grey rubber tip cap and replace it with the protective blue-vented sterile cap (prevents pressure build up).

3.

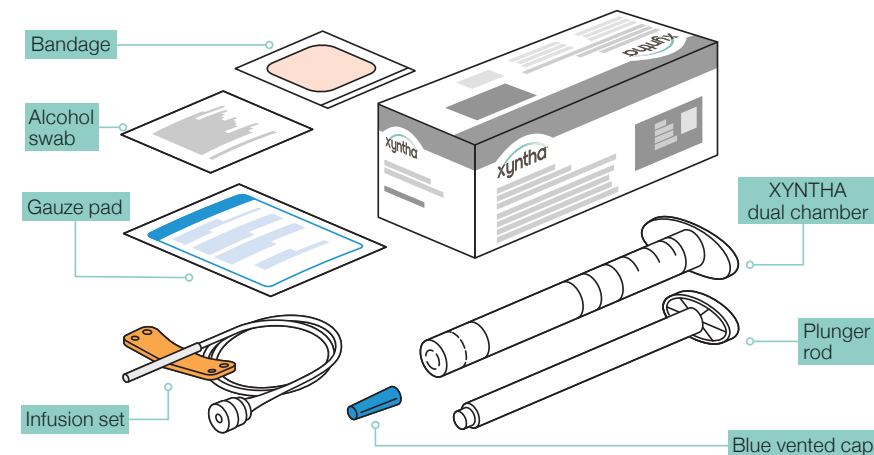


- Gently advance plunger rod until the 2 stoppers inside meet and all the diluent is transferred to the chamber containing the XYNTHA powder.
- Swirl gently several times until powder is dissolved.
- Slowly advance the plunger rod until most, if not all, of the air is removed from the drug product chamber.

## After Reconstitution.

The reconstituted solution should be used as soon as possible after dissolving the powder. If storage after reconstitution is necessary you should store the syringe with the protective blue-vented cap in an upright position, at 2 - 8°C and use within 3 hours.

Only use solutions that are clear and colourless. Use only the accessories provided in the box for reconstitution and administration.



THE ALL-IN-ONE DEVICE ELIMINATES THE TRANSFER STEP.

# HOW TO ADMINISTER

**XYNTHA dual chamber should be administered using the infusion set in your kit. You can use the syringe provided or, if more than one vial is needed, a large sterile disposable plastic luer lock syringe may be available from your Haemophilia Treatment Centre.**

1. Attach the syringe to the luer end of the infusion set.
2. Apply a tourniquet and prepare the injection site by wiping the skin well with an alcohol swab provided in the kit.

3. Insert the needle on the infusion set tubing into the vein and remove the tourniquet.

4. The reconstituted XYNTHA should be injected intravenously over several minutes. The rate of administration should be determined by your comfort level.

5. After completion of XYNTHA treatment remove the infusion set and discard appropriately.

**Contact your doctor or nurse if you have any questions on how to administer.**

# STORING XYNTHA

**The following information applies to XYNTHA moroctocog alfa (rch) (recombinant coagulation factor VIII)**

## **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. Keep the pre-filled syringe in the outer carton in order to protect from light. Keep XYNTHA and contents where young children cannot reach. Do not use XYNTHA beyond the date (month and year) printed on the label.

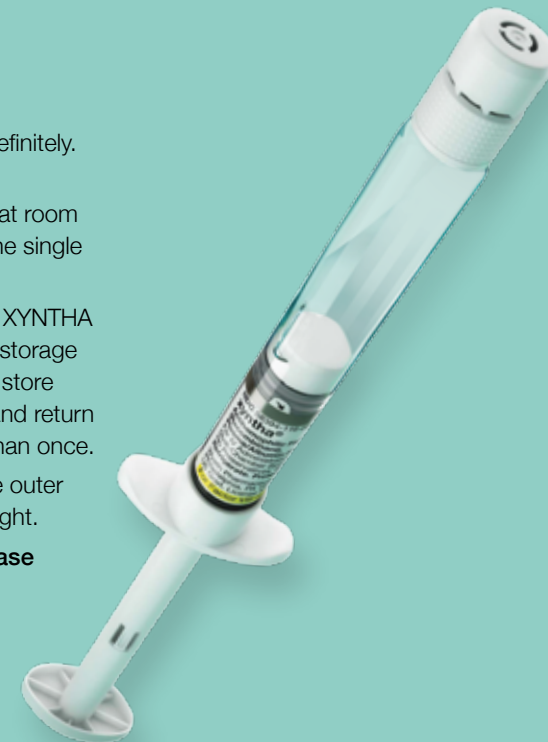
Medicines cannot be stored indefinitely.

XYNTHA may be removed from refrigerated storage and stored at room temperature (below 25°C) for one single period of maximum 3 months.

After room temperature storage, XYNTHA may be returned to refrigerated storage until the expiration date. Do not store XYNTHA at room temperature and return it to refrigerated storage more than once.

Keep the pre-filled syringe in the outer carton in order to protect from light.

**If you have any questions please contact your doctor or nurse.**



# DURING TREATMENT

## Potential side effects.

All medicines can have side effects, but not everybody gets them. If you have been taking a factor VIII replacement therapy for some time, you probably know the kinds of side effects to look out for.

Studies with XYNTHA have shown that per infusion side effects do not occur very often. If they occurred, most reactions were mild or moderate. See list opposite.

**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 and they worry you:**

### **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

### **Breathing 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.



# WHAT TO LOOK OUT FOR

There are a few important things you need to keep in mind whenever you use XYNTHA.

Stop using XYNTHA immediately and contact your doctor or seek emergency care if you develop any allergic signs such as:

- 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.

Contact your doctor or nurse at your Haemophilia Treatment Centre immediately if your bleeding isn't controlled with your usual dose or you are concerned about any side effects (including any not listed here).

Don't be alarmed by this list of possible side effects as you may not experience any of them.



# TRAVELLING

**With a bit of extra forward planning you can travel with peace of mind about your treatment.**

Tell your Haemophilia Treatment Centre about your trip well in advance.

Tell your tour operator or travel agent about your haemophilia and any special requirements when you book.

Make sure you have enough XYNTHA and equipment for your travels (for long trips, it may be possible to have XYNTHA delivered to you by Pfizer, depending on where you are).

Pack your XYNTHA and equipment in a separate case allowing easy access for inspections or infusion (keep it with you so it doesn't get lost, broken or affected by temperature variations in the aircraft hold).

You can get a special Pfizer Travel Pack to keep all of your medication in when you're travelling. If you'd like one just ask your Haemophilia Treatment Centre.

When travelling overseas, you must also remember to obtain a letter from your Haemophilia Treatment Centre to assist clearance of your medical supplies through customs.

And lastly, if you receive a regular XYNTHA delivery, remember to cancel it when you are away.



# ANY QUESTIONS?

This booklet does not contain everything you need to know during your ongoing treatment.  
Your most valuable information source is always your doctor/nurse and/or Haemophilia Treatment Centre.

**Auckland**  
Haematology Department  
Auckland City Hospital  
2 Park Road, Grafton  
Private Bag 92024 Victoria St. West  
Auckland 1142  
Ph: 09 307 2829

**Waikato**  
Haematology Department  
Waikato Hospital  
Pembroke Street, Hamilton  
Private Bag 3200  
Waikato Mail Centre 3420  
Ph: 07 839 8899

**Christchurch**  
Haematology Department  
Christchurch Hospital  
Riccarton Ave  
Private Bag 4710  
Christchurch 8140  
Ph: 03 364 1246

**Palmerston North**  
Haematology Department  
Palmerston North Hospital  
50 Ruahine Street,  
Private Bag 11036  
Palmerston North 4442  
Ph: 06 350 8770

**Wellington**  
Blood and Cancer Centre  
Wellington Hospital  
Riddiford Street, Newtown  
Private Bag 7902  
Wellington South 6242  
Ph: 04 806 2101

**Dunedin**  
Haematology Department  
Dunedin Hospital  
201 Great King St, Dunedin  
Private Bag 1921  
Dunedin 9054  
Ph: 03 474 0999

## The Haemophilia Foundation of New Zealand

It's well worth joining the Haemophilia Foundation of New Zealand for further support, and to stay up to date with any new developments in the treatment of haemophilia. You can contact the foundation at **www.haemophilia.org.nz** or phone the National Office on **0508 FACTOR (322867)**.

# GLOSSARY OF COMMON HAEMOPHILIA TERMS

<b>Albumin</b>	A protein found in human and animal blood.
<b>Antibody</b>	A protein released by the immune system to fight foreign substances that enter the body.
<b>Bleed</b>	Bleeding into muscles, organs and joint spaces.
<b>Clinical Trials</b>	Carefully controlled studies that test the safety and efficacy of medications.
<b>Coagulation</b>	Normal clotting process that arrests bleeding.
<b>Factor</b>	A blood protein involved in the normal clotting process (coagulation); also a shortening of the term 'factor replacement therapy', i.e. XYNTHA.
<b>Factor VIII</b>	A clotting factor protein needed for coagulation; low in people with haemophilia A.
<b>Factor IX</b>	A clotting factor protein needed for coagulation; low in people with haemophilia B.
<b>Haemorrhage</b>	Severe bleeding.
<b>Hereditary</b>	Passed on from parents to children through genes.
<b>Infusion</b>	Administration of factor replacement therapy.

<b>Inhibitor</b>	An antibody that neutralises a coagulation factor and interferes with its function, leading to treatment complications.
<b>Nanofiltration</b>	Additional step in the XYNTHA purification process involving a tiny 35 nanometre filter.
<b>On-demand treatment</b>	Using factor replacement in response to a bleeding episode or injury.
<b>Ports</b>	Devices implanted under the skin to improve vein access; often used in young children.
<b>Prophylaxis</b>	Using factor replacement as a preventative treatment.
<b>Synthetic ligand</b>	Man-made molecule in the XYNTHA purification process.
<b>TRACKER FACTORY</b>	A free program for recording and tracking bleeds and infusions by accessing <a href="http://www.trackerfactory.co.nz">www.trackerfactory.co.nz</a>
<b>Von Willebrand's disease (VWD)</b>	Deficiency in the clotting protein called von Willebrand factor.

# ORDERING AND DELIVERY OF XYNTHA

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Xyntha is manufactured by Pfizer. Pfizer has a special Haemophilia Direct Delivery Program that is run in conjunction with your Haemophilia Treatment Centre.

For more detailed information on this program, there is a comprehensive booklet available. Just ask your Haemophilia Treatment Centre for a copy.

**If you want to keep a record of your centre's contact details, just write them down here.**

Contact name/s: .....

Phone: .....

E-mail: .....

Postal address: .....

**XYNTHA has risks and benefits.**

**XYNTHA (moroctocog alfa (rch) (recombinant coagulation factor VIII)) 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU**

XYNTHA (moroctocog alfa (rch)) is a funded medicine that is prescribed by a doctor for the control and treatment of bleeding and the routine and surgical prevention of bleeding in patients with haemophilia A. A pharmacy charge and normal doctor's fees apply. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your doctor if you have had an allergic reaction to hamster protein or any of the other ingredients of XYNTHA. XYNTHA must be used with caution in certain people, including: people with factor VIII inhibitors, people with allergies, people changing from other factor VIII medicines to XYNTHA, and pregnant or breastfeeding women. Ask your doctor for advice. Uncommon to very rare serious side effects include numbness, chest pain, rapid or irregular heartbeat, shortness of breath, bleeding and low blood pressure. If you have side effects see your doctor. If you suddenly experience a swollen face, lips, tongue or throat, shortness of breath, chest tightness, wheezing, dizziness, faintness, chills, flushing, tiredness, restlessness, nausea, vomiting, rapid heartbeat, headache, tingling, burning and stinging at the injection site, hives or skin rash, STOP taking XYNTHA and seek urgent medical attention. These may be signs of a serious allergic reaction. Tell your doctor immediately if you are using increasing amounts of XYNTHA in order to control a bleeding episode. Use strictly as directed. Consult your doctor to see if XYNTHA is right for you. Contains moroctocog alfa (rch) 250, 500, 1000, 2000, 3000 IU/vial or syringe.

Further information on XYNTHA is available from [www.medsafe.govt.nz](http://www.medsafe.govt.nz) or Pfizer New Zealand Limited, Auckland, [www.pfizer.co.nz](http://www.pfizer.co.nz). Ph. 0800 736 363. V11216. Pfizer New Zealand, Level 1, Suite 1.4, Building B, 8 Nugent Street, Grafton, Auckland 1023. PZR0314 PP-XYN-ANZ-0015 NA 9403 09/17.

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