

START HERE

Ready. Set. Reconstitute.

www.haemophilia.co.nz

xyntha
dual chamber
Moroctocog alfa rch
(recombinant coagulation factor VIII)

DISCOVER MY TOOLKIT

Welcome to XYNTHA® (moroctocog alfa (rch))

This travel kit should include everything you need to infuse on the go.

WHAT IS XYNTHA?

XYNTHA is indicated for the control and prevention of haemorrhagic episodes in patients with haemophilia A, including control and prevention of bleeding in surgical settings. XYNTHA does not contain von Willebrand factor and should not be used by patients with von Willebrand's disease.

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.

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, it's ready to go when you are.



PREPARATION

- Allow the XYNTHA dual chamber syringe to reach room temperature.
- Always wash your hands before performing the following procedures.
- Place components of the kit on a clean surface.
- Use all components for the reconstitution and administration of this product as soon as possible after opening their sterile containers to minimise unnecessary exposure to the atmosphere.
- Throughout the reconstitution process keep the XYNTHA syringe upright to prevent possible leakage.

DUAL CHAMBER RECONSTITUTION GUIDE

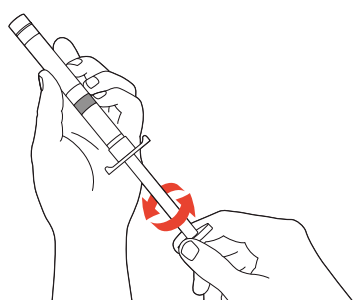
Reconstitution Steps

1

Ready

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

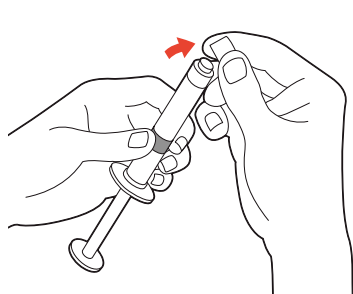
Avoid contact with shaft of the plunger rod.



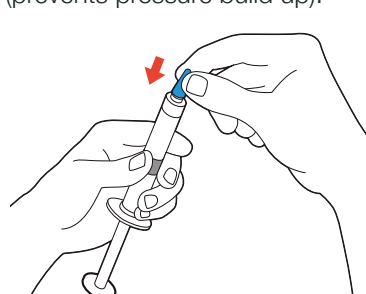
2

Set

A. Remove the white tamper-evident seal by bending the seal to expose the rubber tip cap.



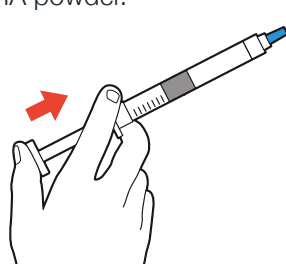
B. Remove the grey rubber tip cap and replace it with the protective blue-vented sterile cap (prevents pressure build up).



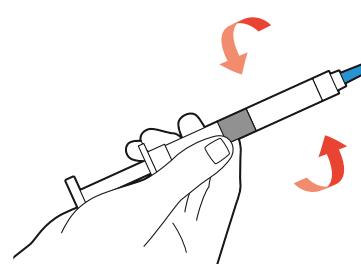
3

Reconstitute

A. Gently advance plunger rod until the 2 stoppers inside meet and all the diluent is transferred to the chamber containing the XYNTHA powder.

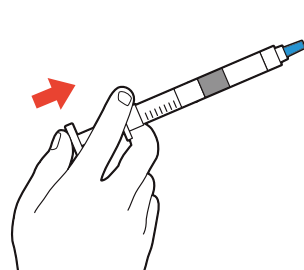


B. Swirl gently several times until powder is dissolved.



C. Slowly advance the plunger rod until most, if not all, of the air is removed from the drug product chamber.

Please note: the solution should be clear to slightly opalescent and colourless. If it is not, the solution should be discarded and a new kit should be used.



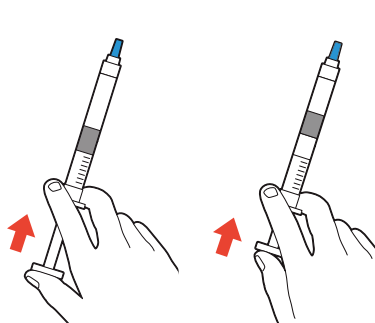
MULTI-DOSE RECONSTITUTION GUIDE

Combining multiple XYNTHA® dual chamber syringes

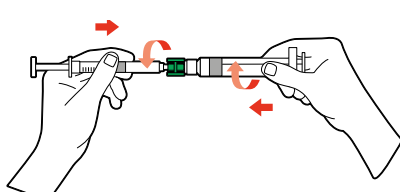
The instructions below are for the use of multiple XYNTHA dual chamber syringes with a 10mL or larger luer lock syringe.

Instructions

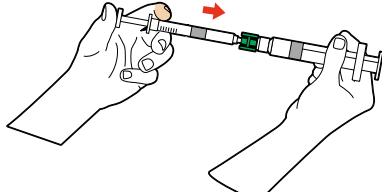
- Reconstitute each XYNTHA dual chamber syringe according to instructions included with each kit.
- Remove the green syringe connector from its package and the protective blue vented cap from its package.



- Connect a 10mL or larger luer lock syringe to one end of the green syringe connector and the XYNTHA dual chamber syringe to the opposite end of the green syringe connector.



- With the XYNTHA dual chamber syringe on top, slowly push the plunger rod until the contents empty into the 10mL or larger luer lock syringe.



- Remove empty XYNTHA dual chamber syringe and attach any additional XYNTHA dual chamber reconstituted syringes to the green syringe connector in order to empty contents into the 10mL or larger luer lock syringe.
- Remove the green syringe connector and attach the 10mL or larger luer lock syringe to the infusion set included inside the XYNTHA dual chamber syringe kit.

For further information about your treatment or condition, see your healthcare professional.

Available in a range of dosing options:

- 250 IU
- 500 IU
- 1000 IU
- 2000 IU
- 3000 IU



STORING XYNTHA

Before reconstitution

- Store and transport refrigerated (2-8°C).
- Do not freeze.
- 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.

After reconstitution

- The reconstituted solution should be used as soon as possible. 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.

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 or Pfizer New Zealand Limited, Auckland, www.pfizer.co.nz. Ph. 0800 736 363.

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Pfizer New Zealand, Level 1, Suite 1.4, Building B, 8 Nugent Street, Grafton, Auckland 1023.

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