

XYNTHA[®] POWDER AND SOLVENT FOR SOLUTION FOR INJECTION

Moroctocog alfa (250 IU, 500 IU, 1000 IU or 2000 IU)Xyntha

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What XYNTHA is used for

XYNTHA is an injectable medicine that is used to help control and reduce bleeding in people with hemophilia A (a bleeding disorder in which the blood does not clot properly).

XYNTHA is also used after surgery.

XYNTHA is not used to treat von Willebrand's disease (A bleeding disorder caused by low levels of clotting protein in the blood).

XYNTHA is appropriate for use in children of all ages, including newborns.

How XYNTHA works

XYNTHA temporarily replaces the missing clotting factor VIII that is needed for effective bleeding stoppage and repairing the damage of injury.

Before you use XYNTHA

- When you must not use it

Do not take XYNTHA

- if you are hypersensitive (allergic) to XYNTHA or to any of the other ingredients of the medicine.

Pregnancy and lactation

Consult your doctor if you are pregnant, trying to get pregnant or think you may be pregnant.

It is not known if XYNTHA may harm your unborn baby or passes into your milk and if it can harm your baby.

Do not take XYNTHA if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor, pharmacist or nurse before taking XYNTHA:

- if you have a symptoms of allergic reaction like rash with itching, chest tightness, wheezing, low blood pressure.

Discontinue XYNTHA if allergic symptoms occur and administer appropriate emergency treatment.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use XYNTHA

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Dosing for control and prevention of in bleeding episode

Minor - In conditions like early bleeding into joint, minor muscle or oral bleeds, the dose of XYNTHA is 20 to 40 IU/dL every 12 to 24 hours, for at least 1 day, depending upon the severity of the bleeding episode.

Moderate - In conditions like bleeding into muscles, mild head trauma or bleeding into the oral cavity, the dose of XYNTHA is 30 to 60 IU/dL every 12 to 24 hours, for 3 to 4 days or until adequate local bleeding stoppage and repairing the damage of injury is

achieved.

Major - In conditions like gastrointestinal bleeding, intracranial, intra-abdominal or intrathoracic bleeding, fractures, the dose of XYNTHA is 60 to 100 IU/dL every 8 to 24 hours, until bleeding is resolved.

Dosing for before a surgical operation management

Minor - In conditions like minor operations, including tooth extraction, the dose of XYNTHA is 30 to 60 IU/dL every 12 to 24 hours, for 3 to 4 days or until adequate local bleeding stoppage and repairing the damage of injury is achieved. For tooth extraction, a single infusion plus oral antifibrinolytic (drug that helps the blood clot) therapy within 1 hour may be sufficient.

Major - In Major operations, the dose of XYNTHA is 60 to 100 IU/dL every 8 to 24 hours, until threat is resolved or in the case of surgery bleeding or wound healing is resolved.

Dosing for routine preventive procedure

Adults and adolescents (≥12 years) -

The recommended starting dose of XYNTHA is 30 IU/kg 3 times weekly.

Children (<12 years) - The recommended starting dose of XYNTHA is 25 IU/kg every other day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking XYNTHA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on

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what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give XYNTHA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

If the medicine make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, XYNTHA can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effects:

- headache;
- pain in a joint;
- fever;
- cough.

Other possible side effects:

- diarrhoea;
- vomiting;
- weakness.

Side effects reported during post-marketing experience:

- inadequate therapeutic response.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of XYNTHA

- Storage

Keep out of the reach and sight of children.

Do not freeze.

Protect from light.

Store under refrigeration at a temperature of 2°C to 8°C for up to 3 years.

Store under 25°C at room temperature for up to 3 months only once till expiry date. Do not store at room temperature and return it to the refrigerator more than once.

Diluents syringe may be stored at 2°C to 25°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

XYNTHA powder and solvent for solution for injection for intravenous administration contain 250 IU, 500 IU, 1000 IU or 2000 IU white to off-white lyophilized powder.

- Ingredients

- Active ingredient
Antihemophilic factor (recombinant).

- Inactive ingredients
Sodium chloride, L-histidine, sucrose, polysorbate 80, calcium chloride, dihydrate, 1N HCl, water for Injection.

MAL number

<u>Product Name</u>	<u>Registration Number</u>
XYNTHA 250 IU powder and solvent for solution for injection	MAL20091989AZ
XYNTHA 500 IU powder and solvent for solution for injection	MAL20091990AZ
XYNTHA 1000 IU powder and solvent for solution for injection	MAL20091991AZ
XYNTHA 2000 IU powder and solvent for solution for injection	MAL20091992AZ

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Manufacturer

Manufactured by
Wyeth Farma S.A., Madrid, Spain.

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
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Date of Revision

16/01/2023

Serial Number

NPRA (R3/01)12012023/0236

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Instructions for Use

XYNTHA[®]

[Antihemophilic Factor (Recombinant)]

XYNTHA is supplied as a lyophilized powder. Before you can infuse it (intravenous injection), you must reconstitute the powder by mixing it with the liquid diluent supplied. The liquid diluent is 0.9% sodium chloride.

Reconstitute and infuse XYNTHA using the infusion set, diluent, syringe, and adapter provided in this kit. Please follow the directions below for the proper use of this product.

Preparation and Reconstitution

Preparation:

1. Always wash your hands before doing the following steps.
2. Keep everything clean and germ-free while you are reconstituting XYNTHA.
3. Once the vials are open, finish reconstituting XYNTHA as soon as possible. This will help to keep them germ-free.

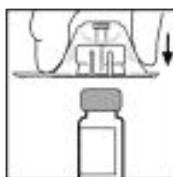
Reconstitution:

Note: If you use more than one vial of XYNTHA for each infusion, reconstitute each vial according to steps 1 through 11.

1. Let the XYNTHA vial and the prefilled diluent syringe reach room temperature.
2. Remove the plastic flip-top cap from the XYNTHA vial to show the centre part of the rubber stopper.



3. Wipe the top of the vial with the alcohol swab provided, or use another antiseptic solution, and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.
4. Peel back the cover from the clear plastic vial adapter package. **Do not remove the adapter from the package.**
5. Place the XYNTHA vial on a flat surface. While holding the adapter in the package, place the vial adapter over the XYNTHA vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike going into the vial stopper.



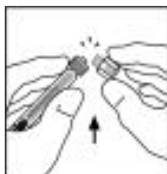
6. Grasp the plunger rod as shown in the picture below. Do not touch the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe plunger by pushing and turning firmly.



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7. Break off the tamper-resistant, plastic tip cap from the diluent syringe by snapping the perforation of the cap. Do not touch the inside of the cap or the syringe tip. The diluent syringe may need to be recapped (if reconstituted XYNTHA is not used immediately), so place the cap on its top on a clean surface in a spot where it will stay clean.



8. Lift the package cover away from the adapter and throw the package away.



9. Place the XYNTHA vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



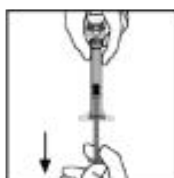
10. Slowly push the plunger rod to inject all the diluent into the XYNTHA vial.



11. With the syringe still connected to the adapter, gently swirl the contents of the vial until the powder is dissolved.

Look carefully at the final solution. The solution should be clear to slightly opalescent and colourless. If it is not, throw away the solution and use a new kit.

12. Make sure the syringe plunger rod is still fully pressed down, then turn over the XYNTHA vial. Slowly pull the solution into the syringe. Turn the syringe upward again and remove any air bubbles by gently tapping the syringe with your finger and slowly pushing air out of the syringe.



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13. Remove the syringe from the vial adapter by gently pulling and turning the syringe counter clockwise. Throw away the empty XYNTHA vial with the adapter attached.

Note:

- If you are not using the solution right away, carefully replace the syringe cap. Do not touch the syringe tip or the inside of the cap.
- Infuse XYNTHA solution within 3 hours after reconstitution. The reconstituted solution may be kept at room temperature for up to 3 hours prior to infusion. If you have not used it in 3 hours, throw it away.

Infusion of XYNTHA

Your healthcare provider will teach you how to infuse XYNTHA yourself. Once you learn how to do this, you can follow the instructions in this insert.

Before XYNTHA can be infused, you must reconstitute it as instructed above in the **Preparation and Reconstitution** of XYNTHA section.

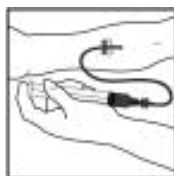
After reconstitution, be sure to look carefully at the XYNTHA solution. The solution should be clear to slightly opalescent and colourless. If it is not, throw away the solution and use a new kit.

Use the infusion set included in the kit to infuse XYNTHA. Do not infuse XYNTHA in the same tubing or container with other medicines.

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



3. Remove the protective needle cover and insert the butterfly needle of the infusion set tubing into your vein as instructed by your healthcare provider. Remove the tourniquet. Verify proper needle placement.
4. Infuse the reconstituted XYNTHA product over several minutes. Your comfort level should determine the rate of infusion.

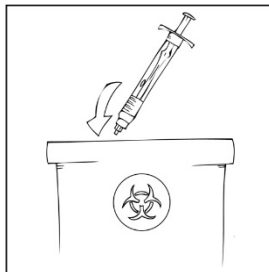


5. After infusing XYNTHA, remove the infusion set and throw it away. The amount of liquid left in the infusion set will not affect your treatment.

Note: Dispose of all unused solution, the empty vial(s), and other used medical supplies in an appropriate container.

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