Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

XYNTHA® 250 IU
XYNTHA® 500 IU
XYNTHA® 1000 IU
XYNTHA® 2000 IU

Lyophilized powder and diluent for solution for intravenous (IV) injection

Each vial contains:
Moroctocog Alfa 250IU, 500IU, 1000IU, 2000IU

For a list of inactive ingredients and allergens, see section 6, 'Further information.'

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency).

Therapeutic group: coagulation factor.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if you have had immediate, life-threatening sensitivity reaction, including anaphylaxis, to the active ingredient or to any of the other ingredients in this medicine, which are listed in section 6, including sensitivity to protein derived from hamster.

Special warnings regarding use of the medicine

Contact your doctor immediately if bleeding is not controlled after injecting the medicinal product.

Before treatment with XYNTHA®, tell your doctor if:
• you have any allergies, including an allergy to hamsters.
• you are pregnant or are planning to become pregnant.
• you are breastfeeding or are planning to breastfeed.

Children and adolescents
XYNTHA® may be used in children and adolescents of all ages.

Tests and follow-up
Your body may produce antibodies to the medicinal product, that may reduce the efficacy of the medicinal product. The attending doctor may ask you to take periodic blood tests to monitor these antibodies in your blood.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding and fertility
Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. It is not known whether XYNTHA® may harm your unborn baby. Consult your doctor before using XYNTHA®.

Tell your doctor if you are breastfeeding or are planning to breastfeed. It is not known whether the medicine passes into breast milk or whether it may harm your baby.

3. HOW TO USE THIS MEDICINE?

XYNTHA® is marketed as a lyophilized powder and diluent in a syringe. Before infusion, the powder must be reconstituted with the diluent included in the package. XYNTHA® is administered as an intravenous injection. Do not swallow.

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the preparation.

The dosage and treatment regimen will be determined by your doctor only.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, contact your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop the treatment with this medicine without consulting a doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of XYNTHA® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

An allergic reaction may occur during treatment with XYNTHA®. If any of the following symptoms appear, immediately contact your doctor or go to the emergency room: wheezing, breathing difficulties, chest tightness, turning blue (bluish lips and gums), fast heartbeat, swelling of the face, weakness, rash, urticaria.

Additional side effects include:

Common side effects (affect 1-10 in 100 users):
headache, fever, nausea, vomiting, diarrhea, weakness.

Additionally, your body may produce antibodies to the medicinal product that may reduce the efficacy of the medicinal product.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by using the link: https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Before reconstitution: Store in the refrigerator (2°C-8°C). **Do not freeze.**

Protect from light.

The medicinal product may also be stored outside the refrigerator below 25°C on a one-time basis for 3 months but no later than the expiry date. Discard any remaining unused quantity that was not refrigerated during this period. Do not return to the refrigerator.

After reconstitution: Use within 3 hours.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
sodium chloride, sucrose, l-histidine, calcium chloride, polysorbate 80.

The syringe contains: 0.9% sodium chloride solution.

What the medicine looks like and contents of the pack:

XYNTHA® is marketed as a white powder in a vial and a clear colorless diluent in a syringe.

Each package contains:
1 vial of powder containing recombinant coagulation factor VIII in 250, 500, 1000 or 2000 IU per vial.
1 syringe containing 4 ml of diluent (0.9% sodium chloride solution).
1 plunger rod for assembly.
1 vial adapter.
1 sterile infusion set.
2 alcohol swabs.
1 bandage.
1 gauze pad.

Not all strengths of the medicinal product may be marketed.

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

Manufacturer's name and address:
Wyeth Farma S.A., Madrid, Spain.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
XYNTHA® 250 IU: 137-78-31591
XYNTHA® 500 IU: 137-79-31592
XYNTHA® 1000 IU: 137-80-31593
XYNTHA® 2000 IU: 137-81-31594

INSTRUCTIONS FOR USE

Please read these entire instructions before using XYNTHA®. Follow these instructions step by step. Please do not use this medicinal product unless the medical team had provided instruction.

If you do not understand something or if you cannot perform an action, or if you have any questions about the dosage or the treatment with XYNTHA® contact your medical team.

Reconstitution
Wash your hands well with soap and water before using XYNTHA®.

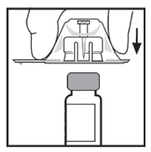
Perform the reconstitution in as clean an environment as possible.

Once you open the vial, complete the reconstitution as quickly as possible.

If you are using more than one vial of XYNTHA®, reconstitute each vial according to steps 1 through 13.

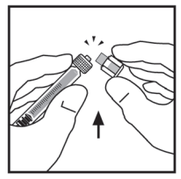
1. If the medicine was stored in the refrigerator, wait until the vial and the diluent syringe reach room temperature.
2. Remove the plastic cap from the vial to expose the vial's rubber stopper.

3. Wipe the vial opening with an alcohol swab provided in the package, and allow the opening to dry. After cleaning, do not touch the vial opening or allow any surface or object to come in contact with the vial opening.
4. Peel back the cover from the vial adapter. **Do not remove the adapter from its package.**
5. Place the vial on a flat surface. While holding the adapter package, place the adapter on the vial. Press down firmly on the adapter package until the adapter snaps into place on the vial opening and the adapter spikes penetrate the vial stopper.

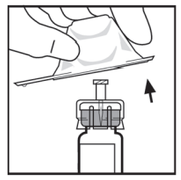


6. Grasp the plunger as shown in the picture. Do not touch the plunger rod. Attach the end of the plunger to the diluent syringe by pushing and turning firmly.

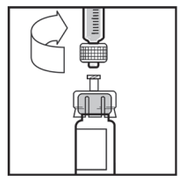
7. Break the plastic cap off the syringe by snapping the perforation. Do not touch the inside of the cap or the syringe tip.



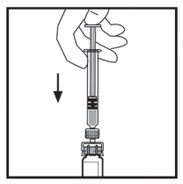
8. Lift the package off the adapter and discard the package.



9. Place the 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 a connection is achieved.



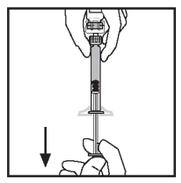
10. Slowly push the plunger to inject all of the diluent into the vial of the medicinal product.



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

    Look at the solution before injecting it. The solution should be clear and colorless. If it is not, discard the vial and use a new kit of the medicinal product.

12. Make sure the syringe plunger is still pressed down, then turn the vial upside down and draw the solution into the syringe. Turn the syringe upwards again and remove air bubbles by gently tapping the syringe with your fingers. If you are using more than one vial of the medicinal product, remove the syringe from the vial adapter and leave the adapter attached to the vial. Quickly connect a large syringe and draw the solution as explained in the steps above. Repeat this same procedure with each vial. Do not separate the diluent syringe or the large syringe until you are ready to connect the large syringe to the next vial adapter.



13. Remove the syringe from the vial adapter by gently pulling and turning the syringe counterclockwise. Discard the vial with the adapter attached. If you are not using the solution immediately, replace the syringe cap. Do not touch the syringe tip or the inside of the cap.

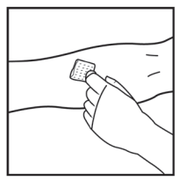
    The medicinal product must be injected within 3 hours after reconstitution. Store the reconstituted solution at room temperature.

Injection

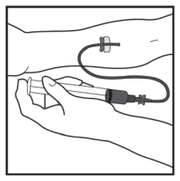
Your attending doctor or nurse will show and teach you how to inject XYNTHA®.

Once you learn how to inject by yourself, follow the instructions in this leaflet.

1. Attach the syringe to the sterile infusion set provided in the medicinal product's package.
2. Apply a tourniquet and prepare the injection site by cleaning the skin well with the alcohol swabs provided in the medicinal product's package.



3. Insert the butterfly needle contained in the infusion set into your vein as instructed by your doctor or nurse. Remove the tourniquet. Inject the medicinal product for several minutes. The rate of infusion depends on the level of comfort you feel.



There have been reports of red blood cell cluster in the syringe during injection of the medicinal product. No resulting side effects have been reported. In order to minimize the accumulation of red blood cells, it is important to limit the amount of blood that enters the tube. Blood should not enter the syringe. If you notice red blood cells accumulating in the tube or in the syringe, discard the entire kit (the syringe with the medicinal product and the infusion set) and use a new kit of the medicinal product.

4. After injecting the medicinal product into your vein, discard the syringe and the infusion set. The amount of medicine left in the infusion set does not affect your treatment. Discard the needle, the vial and the infusion set in an appropriate container.

It is recommended to record the batch number stated on the vial every time you use this medicinal product.

Revised in 11/2020 according to MOH guidelines.