

# INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF XYNTHA

## Reconstitution and Administration of XYNTHA

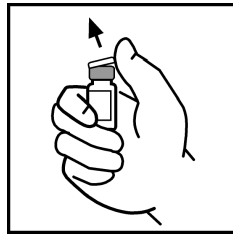
Always wash your hands before doing the following procedures. Use germ-free methods during the making up procedure.

Use only the pre-filled syringe provided in the box for dissolving the XYNTHA powder.

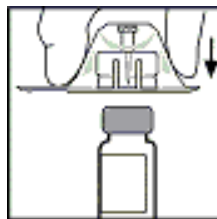
### Mixing the XYNTHA powder with sterile diluent

XYNTHA is given by intravenous injection after mixing the powder with sterile sodium chloride diluent.

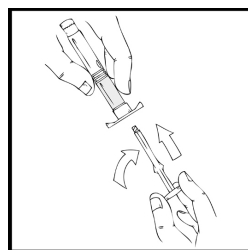
1. Allow the vial of lyophilised XYNTHA and the pre-filled diluent syringe to reach room temperature.
2. Remove the plastic flip-top cap from the XYNTHA vial to expose the central portion of the rubber stopper.



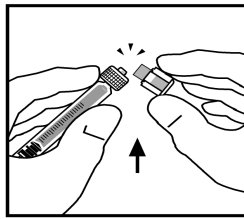
3. Wipe the top of the vial with the alcohol swab provided, or use another antiseptic solution and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface.
4. Peel back the lid from the clear plastic vial adapter package. Do not remove the adapter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



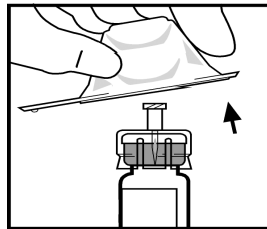
6. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe plunger by pushing and turning firmly.



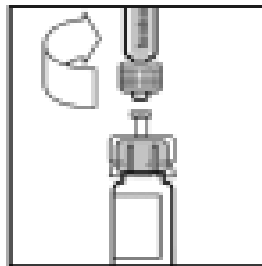
7. Break off the tamper-resistant plastic cap from the diluent syringe by snapping the perforation of the cap. This is done by bending the cap up and down until the perforation is broken. Do not touch the inside of the cap or the syringe tip. The cap may need to be replaced (if not administering reconstituted XYNTHA immediately), so set it aside by placing it on its top.



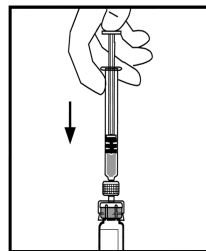
8. Lift the package away from the adapter and discard the package.



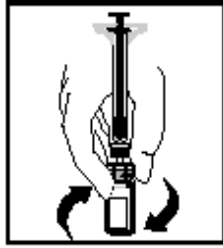
9. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



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



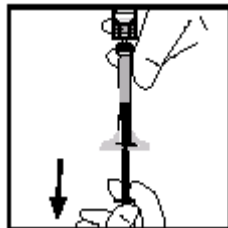
11. With the syringe still connected to the adapter, **gently** rotate the vial until the powder is dissolved.



12. The final solution must be inspected visually for particulate matter before administration. The solution will appear clear to slightly opalescent and colourless.

Note: If you use more than one vial of XYNTHA per infusion, each vial should be reconstituted as per the previous instructions. The diluent syringe should be removed, leaving the vial adapter in place, and a single large luer lock syringe may be used to draw back the reconstituted contents of each of the individual vials.

13. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw back all the solution through the vial adapter into the syringe.



14. Detach the syringe from the vial adapter by gently pulling and turning the syringe counter-clockwise. Discard the vial with the vial adapter attached.

Note: If the solution is not to be used immediately, the syringe cap is to be carefully replaced. Do not touch the syringe tip or the inside of the cap.

### **Use XYNTHA within 3 hours of reconstitution.**

The reconstituted solution should be used as soon as possible after reconstitution. XYNTHA does not contain a preservative. If storage after reconstitution is necessary, refrigerate and use within 3 hours.

### **Administration (Intravenous Injection)**

Your doctor or healthcare professional should teach you how to infuse XYNTHA. Once you learn how to self-infuse, you can follow the instructions in this insert.

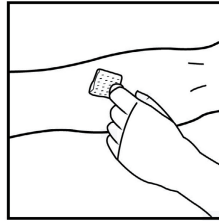
Always wash your hands before doing the following procedures. Use germ-free methods during injection. All components used in the reconstitution and administration of this product should be used as soon as possible after opening their sterile containers to minimise unnecessary exposure to the atmosphere.

Administer XYNTHA by intravenous (IV) injection using the infusion set provided in the kit and the pre-filled diluent syringe or a single sterile disposable plastic luer lock syringe.

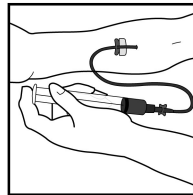
### **Do not mix XYNTHA with other infusion solutions.**

1. Attach the syringe to the luer end of the infusion set tubing provided.

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 butterfly needle of the infusion set tubing into your vein as instructed by your doctor or healthcare professional. Remove the tourniquet. Infuse the reconstituted XYNTHA product over several minutes. Your doctor may change your recommended infusion rate to make the infusion more comfortable.



### **Disposal**

Following completion of XYNTHA treatment, remove the infusion set and discard. Dispose of all unused solution, empty vials and used needles and syringes into a sharps container.

Medicines must not be disposed of down the toilet or via household waste. These measures help protect the environment.