

Guide to all-in-one reconstitution

READY. SET. RECONSTITUTE.

Preparation

- Allow the XYNTHA[®] Dual Chamber syringe to reach room temperature.
- Wash hands before use.
- Place components of the kit on a clean surface.
- Throughout the reconstitution process keep the XYNTHA syringe upright to prevent possible leakage.
- Components should be used as soon as possible after opening.

Reconstitution Steps

• Screw the plunger rod firmly into prefilled Dual Chamber syringe by pushing and turning firmly until resistance is felt.





- 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).
- Gently advance plunger rod by pushing 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, but 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.



Before reconstitution

- Store and transport refrigerated (2-8°C).
- Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- The product may be removed from refrigerated storage for one single period of maximum 3 months at room temperature (up to 25°C).
- At the end of this period of room temperature storage, the product must not be returned to refrigerated storage but either used or discarded.

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 for up to 3 hours.





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