
The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR HEALTH CARE PROFESSIONALS

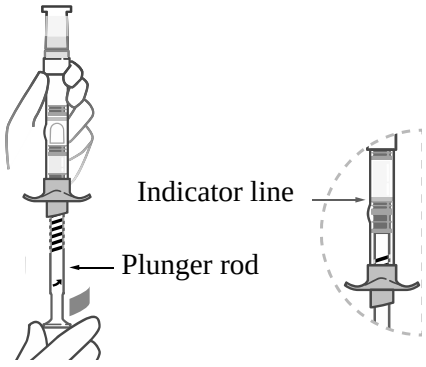
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Abilify Maintena 300 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe
Abilify Maintena 400 mg powder and solvent for prolonged-release suspension for injection in pre-filled syringe
aripiprazole

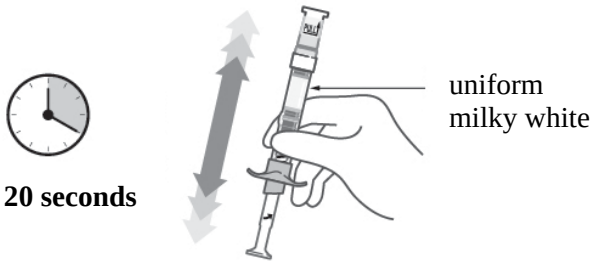
Step 1: Preparation prior to reconstitution of the powder
Lay out and confirm that components listed below are provided:
- Abilify Maintena package leaflet and instructions for healthcare professionals.
- One Abilify Maintena pre-filled syringe.
- One 25 mm (1 inch) 23 gauge hypodermic safety needle with needle protection device.
- One 38 mm (1.5 inch) 22 gauge hypodermic safety needle with needle protection device.
- One 51 mm (2 inch) 21 gauge hypodermic safety needle with needle protection device.
- Syringe and needle instructions.

Step 2: Reconstitution of the powder

a) Push plunger rod slightly to engage threads. And then, rotate plunger rod until the rod stops rotating to release diluent. After plunger rod is at complete stop, middle stopper will be at the indicator line.



b) Vertically shake the syringe vigorously for 20 seconds until the reconstituted suspension appears uniform. The suspension should be injected immediately after reconstitution.

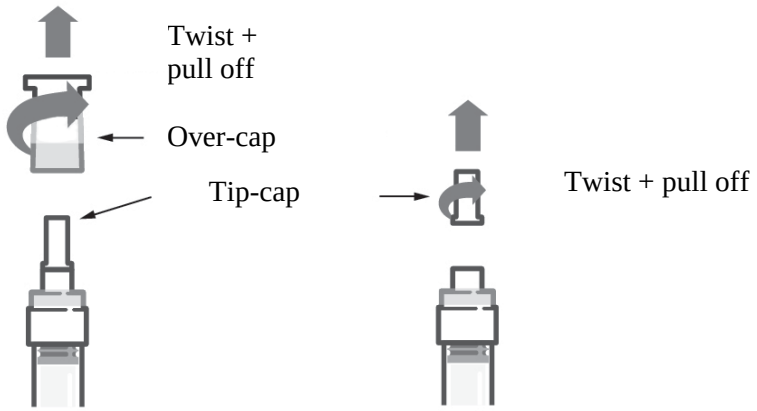


c) Visually inspect the syringe for particulate matter and discoloration prior to administration. The reconstituted product suspension should appear to be a uniform, homogeneous suspension that is opaque and milky-white in colour.

d) If the injection is not performed immediately after reconstitution, the syringe can be kept below 25 °C for up to 2 hours. Shake the syringe vigorously for at least 20 seconds to re-suspend prior to injection if the syringe has been left for more than 15 minutes.

Step 3: Injection procedure

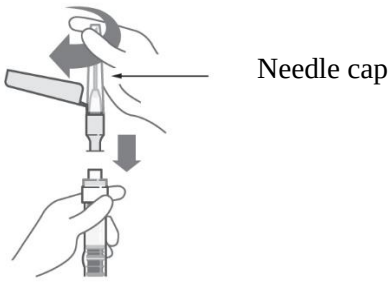
a) Twist and pull off over-cap and tip-cap.



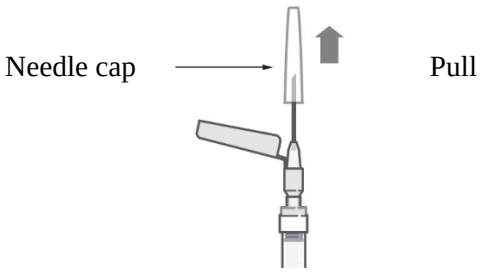
b) Select one of the following hypodermic safety needles depending on the injection site and patient's weight.

Body type	**Injection site**	**Needle size**
Non-obese	**Deltoid** **Gluteal**	**25 mm (1 inch) 23 gauge** **38 mm (1.5 inch) 22 gauge**
Obese	**Deltoid** **Gluteal**	**38 mm (1.5 inch) 22 gauge** **51 mm (2 inch) 21 gauge**

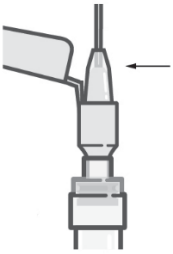
c) While holding the needle cap, ensure the needle is firmly seated on the safety device with a push and twist clockwise until snugly fitted.



d) Then **pull** needle-cap straight up.



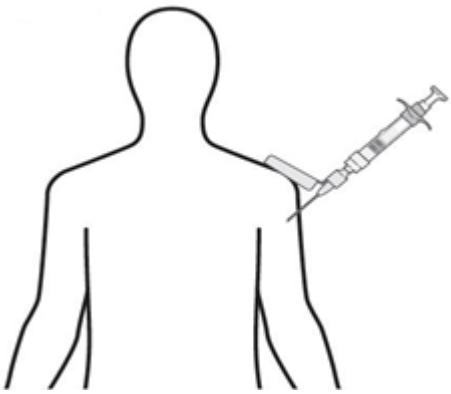
e) Hold syringe **upright and advance plunger rod slowly to expel the air**. If it's not possible to advance plunger rod to expel the air, check that plunger rod is rotated to a complete stop. It is not possible to re-suspend after the air in the syringe is expelled.



Expel air until suspension fills needle base*

***If there's resistance or difficulty expelling air,** check that plunger rod is rotated to a complete stop.

f) Slowly inject into the gluteal or deltoid muscle. Do not massage the injection site. Care must be taken to avoid inadvertent injection into the blood vessel. Do not inject into an area with signs of inflammation, skin damage, lumps and/or bruises. For deep intramuscular gluteal or deltoid injection only.



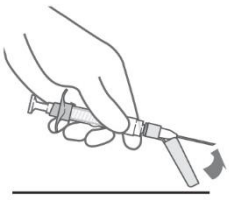
deltoid

gluteal

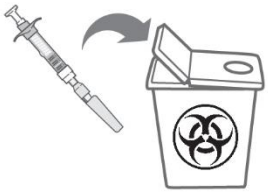
Remember to rotate sites of injections between the two gluteal or deltoid muscles.
If initiating with the two injection start, inject into two different sites in two different muscles.
DO NOT inject both injections concomitantly into the same deltoid or gluteal muscle.
For known CYP2D6 poor metabolisers administer in either two separate deltoid muscles or one deltoid and one gluteal muscle. DO NOT inject into two gluteal muscles.
Look for signs or symptoms of inadvertent intravenous administration.

Step 4: Procedures after injection

Engage the needle safety device. Dispose of the needle and pre-filled syringe appropriately after injection.



Cover



Discard