

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

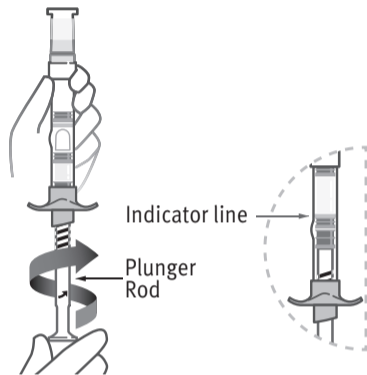
Step 1: Preparation prior to reconstitution of the powder

Lay out and confirm that components listed below are provided:

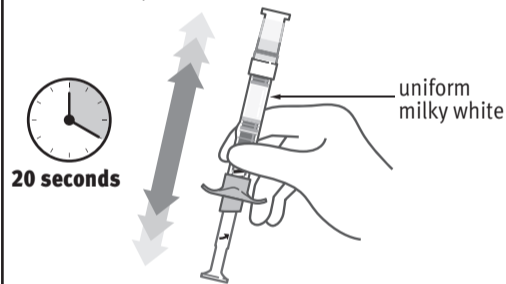
- Abilify Maintena package leaflet and instructions for healthcare professionals
- One Abilify Maintena pre-filled syringe
- One 25 mm (1 inch) 23 gauge hypodermic safety needle with needle protection device
- One 38 mm (1.5 inch) 22 gauge hypodermic safety needle with needle protection device
- One 50 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.

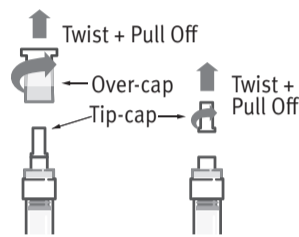


c) Visually inspect the syringe for particulate matter and discoloration prior to administration. The reconstituted product suspension should appear to be a uniform, homogeneous suspension that is opaque and milky-white in color.

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

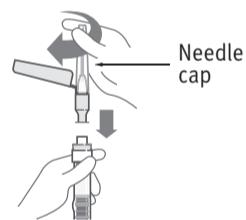
a) Twist and pull off Over-cap and Tip-cap.



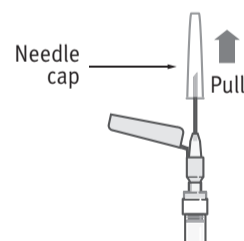
b) Select one of the following hypodermic safety needles depending on the injection site and patient's weight.

Body type	Injection site	Needle size
Non-obese	Deltoid	25 mm (1 inch) 23 gauge
	Gluteal	38 mm (1.5 inch) 22 gauge
Obese	Deltoid	38 mm (1.5 inch) 22 gauge
	Gluteal	50 mm (2 inch) 21 gauge

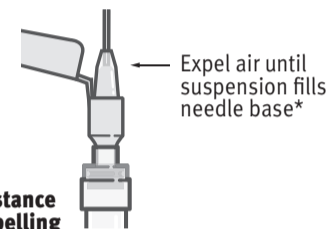
c) While holding the needle cap, ensure the needle is firmly seated on the safety device with a push. Twist clockwise until snugly fitted.



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

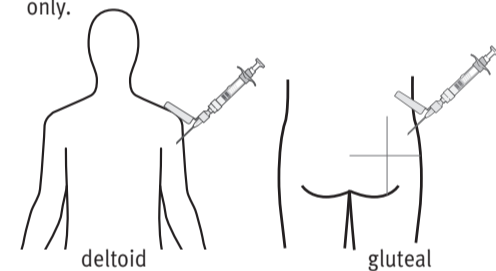


e) Hold syringe **upright and advance plunger rod slowly to expel the air**. If it's not possible to advance plunger rod to expel the air, check that plunger rod is rotated to a complete stop. It is not possible to re-suspend after the air in the syringe is expelled.



***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.



Remember to rotate sites of injections between the two gluteal or deltoid 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.

