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
Abilify Maintena® 400 mg powder and solvent for prolonged-release suspension for injection

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.
- Vial of powder .
- 2 ml vial of solvent.
  Important: the solvent vial contains an overfill.
- One 3 ml luer lock syringe with pre-attached 38 mm (1.5 inch) 21 gauge hypodermic safety needle with needle protection device.
- One 3 ml disposable syringe with luer lock tip.
- One vial adapter.
- 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

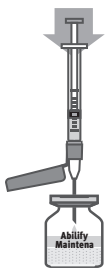
a) Remove the solvent and powder vial caps and wipe the tops with a sterile alcohol swab.

b) Using the syringe with pre-attached needle, withdraw the pre-determined solvent volume from the vial of the solvent into the syringe.

300 mg vial:
Add 1.5 ml solvent to reconstitute the powder.

400 mg vial:
Add 1.9 ml solvent to reconstitute the powder.

A small amount of residual solvent will remain in the vial following withdrawal. Any excess should be discarded.



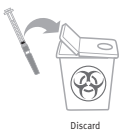
c) Slowly inject the solvent into the vial containing the powder.

d) Withdraw air to equalise the pressure in the vial by pulling back slightly on the plunger.

e) Subsequently, remove the needle from the vial.

Engage the needle safety device by using the one-handed technique.

Gently press the sheath against a flat surface until the needle is firmly engaged in the needle protection sheath.
Visually confirm that the needle is fully engaged into the needle protection sheath, and discard.



f) Shake the vial vigorously for 30 seconds until the suspension appears uniform.

g) Visually inspect the reconstituted suspension for particulate matter and discolouration prior to administration. The reconstituted medicine is a white to off-white, fluid suspension. Do not use if reconstituted suspension contains particulate matter or any discolouration.

h) If the injection is not performed immediately after reconstitution, keep the vial below 25 °C for up to 4 hours and shake it vigorously for at least 60 seconds to re-suspend prior to injection.

i) Do not store the reconstituted suspension in the syringe.

Step 3: Preparation prior to injection

a) Remove the cover, but not the adapter from the package.

b) Using the vial adapter package to handle the vial adapter, attach the pre-packaged luer lock syringe to the vial adapter.

c) Use the luer lock syringe to remove the vial adapter from the package and discard the vial adapter package. Do not touch the spike tip of the adapter at any time.

d) Determine the recommended volume for injection.

Abilify Maintena 300 mg Vial

Dose	Volume to Inject
–	–
300 mg	1.5 ml
200 mg	1.0 ml
160 mg	0.8 ml

Abilify Maintena 400 mg Vial

Dose	Volume to Inject
400 mg	2.0 ml
300 mg	1.5 ml
200 mg	1.0 ml
160 mg	0.8 ml

e) Wipe the top of the vial of the reconstituted suspension with a sterile alcohol swab.

f) Place and hold the vial of the reconstituted suspension on a hard surface. Attach the adapter-syringe assembly to the vial by holding the outside of the adapter and pushing the adapter's spike firmly through the rubber stopper, until the adapter snaps in place.

g) Slowly withdraw the recommended volume from the vial into the luer lock syringe to allow for injection.

A small amount of excess product will remain in the vial.

Step 4: Injection procedure

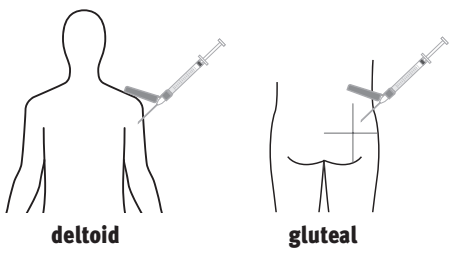
a) Detach the luer lock syringe containing the recommended volume of reconstituted Abilify Maintena suspension from the vial.

b) Select one of the following hypodermic safety needles depending on the injection site and patient's weight and attach the needle to the luer lock syringe containing the suspension for injection. Ensure the needle is firmly seated on the needle protection device with a push and clockwise twist and then pull the needle cap straight away from the needle.

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 50 mm (2 inch) 21 gauge

c) Slowly inject the recommended volume as a single intramuscular injection 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. Look for signs or symptoms of inadvertent intravenous administration.

Step 5: Procedures after injection

Engage the needle safety device as described in Step 2 e). Dispose of the vials, adapter, needles, and syringe appropriately after injection.
The powder and solvent vials are for single-use only.