

FARMEA

		VERSION N°	DATE
Designation : Rispéridone Notice IFU (005U9800200) 957x383 (120x64 Outsert Stanzriss AK1)		V1-1 V1-2 V1-3 V1-4 V1-5 V1-6 V1-7 V1-8 V1-9	12/11/24 20/11/24 29/11/24 04/12/24 13/12/24 17/12/24 18/12/24 20/01/25 21/01/25
Technical information : 957 x 383mm - 2 pages (corps 10pts)			
TECHNICAL APPROVAL <i>To be signed by manufacturing site</i>	FINAL READY FOR PRINT <i>To be signed by Customer</i>		
DIGITAL SIGNATURE	DIGITAL SIGNATURE	COLORS CYANMAGENTA JAUNE NOIR ZONE DE RÉSERVE DU TEXTE	
		PROCESSED BY PMk PitchMark COMMUNICATION	

Important Information

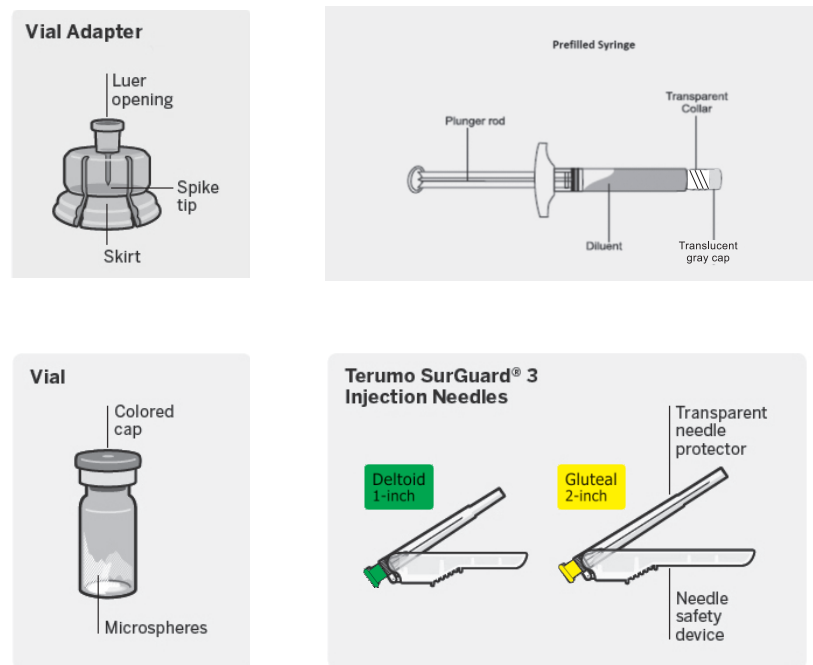
Use components provided
The components in this dose pack are specifically designed for use with risperidone for extended-release injectable suspension. Risperidone for extended-release injectable suspension must be reconstituted only in the diluent supplied in the dose pack.

Do not substitute ANY components of the dose pack.

Do not store suspension after reconstitution
Administer dose as soon as possible after reconstitution to avoid settling.

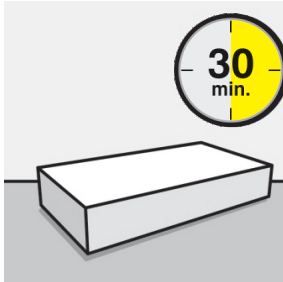
Proper dosing
The entire contents of the vial must be administered to ensure intended dose of risperidone for extended-release injectable suspension is delivered.

Dose Pack Contents



Step 1 Assemble Components

Take out dose pack



Wait 30 minutes. Remove dose pack from the refrigerator and allow to sit at room temperature for at least **30 minutes** before reconstituting.

Do not warm any other way.

Connect vial adapter to vial

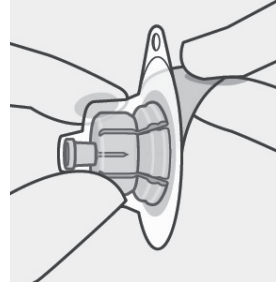


Remove cap from vial. Flip off colored cap from vial.

Wipe top of the gray stopper with an alcohol swab.

Allow to air dry.

Do not remove gray rubber stopper.



Prepare vial adapter. Hold sterile blister as shown. Peel back and remove paper backing.

Do not remove vial adapter from blister.

Do not touch spike tip at any time. This will result in contamination.



Connect vial adapter to vial

Place vial on a hard surface and hold by the base. Center vial adapter over the gray rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place.

Do not place vial adapter on at an angle or diluent may leak upon transfer to the vial.



Connect prefilled syringe to vial adapter



Remove sterile blister

Remove vial adapter from sterile blister only when you are ready to remove the translucent gray cap from the prefilled syringe

Keep vial vertical to prevent leakage.

Hold base of vial and pull up on the sterile blister to remove.

Do not shake.

Do not touch exposed luer opening on vial adapter.

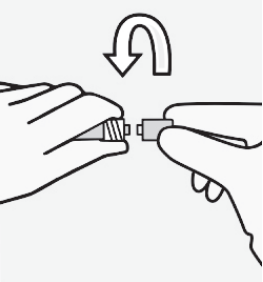
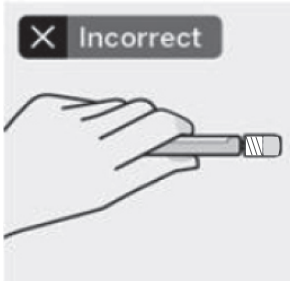
This will result in contamination.



Use proper grip

Hold by transparent collar at the tip of the syringe.

Do not hold syringe by the glass barrel during assembly.

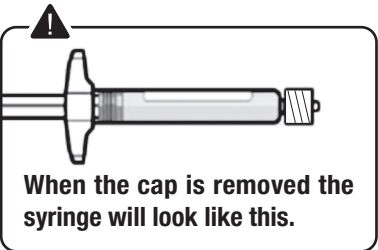


Remove cap

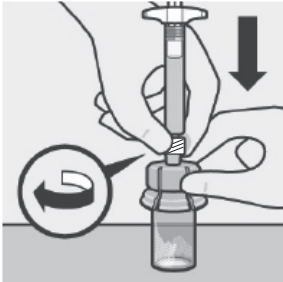
Holding the transparent collar, unscrew the translucent gray cap by turning it counter clockwise.

DO NOT SNAP OR CUT OFF THE TRANSLUCENT GRAY CAP.

Do not touch the syringe tip. This will result in contamination.



The unscrewed cap can be discarded.



Connect syringe to vial adapter

Hold vial adapter by skirt to keep stationary.

Hold syringe by transparent collar then insert tip into the luer opening of the vial adapter.

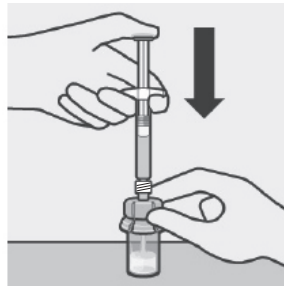
Do not hold the glass syringe barrel. This may cause the transparent collar to loosen or detach.

Attach the syringe to the vial adapter with a firm **clockwise twisting motion** until it feels snug.

Do not over-tighten. Over-tightening may cause the syringe tip to break.

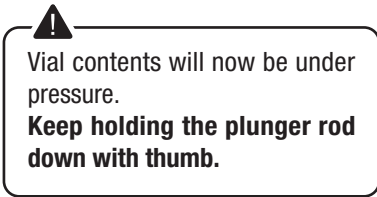
Risperidone for extended-release injectable suspension, 25 mg/Vial, 37.5 mg/Vial and 50 mg/Vial
Instructions for Use
Risperidone for extended-release injectable suspension, 25 mg/Vial, 37.5 mg/Vial and 50 mg/Vial
Injection only
PLEASE READ COMPLETE INSTRUCTIONS
Prior to use ensure successful administration.
Do not reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.
IMPORTANT RESOURCES
For additional information, call Lupin Pharmaceuticals Inc. at 1-800-399-2561.

Step 2 Reconstitute microspheres



Inject diluent

Inject entire amount of diluent from syringe into the vial.



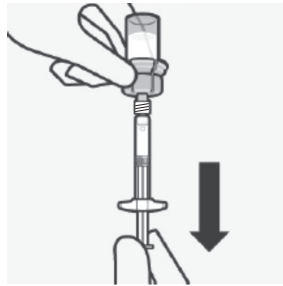
Suspend microspheres in diluent

Continuing to hold down the plunger rod, **shake vigorously for at least 10 seconds**, as shown.

Check the suspension.

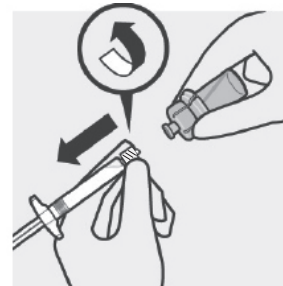
When properly mixed, the suspension appears uniform, thick and milky in color.

Microspheres will be visible in the liquid. Immediately proceed to the next step so suspension does not settle.



Transfer suspension to syringe

Invert vial completely. Slowly pull plunger rod down to withdraw entire contents from the vial into the syringe.



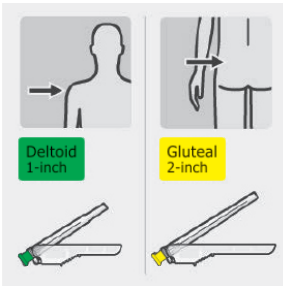
Remove vial adapter

Hold transparent collar on the syringe and unscrew from vial adapter.

Tear section of the vial label at the perforation. Apply detached label to the syringe for identification purposes.

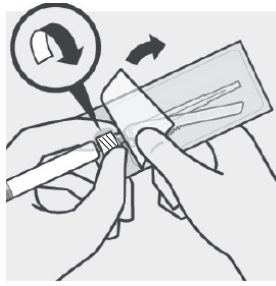
Discard both vial and vial adapter appropriately.

Step 3 Attach needle



Select appropriate needle

Choose needle based on injection location (gluteal or deltoid).

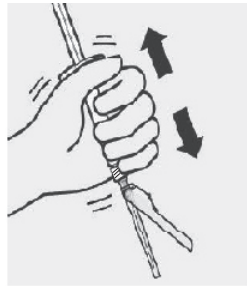


Attach needle

Peel blister pouch open part way and use to grasp the base of the needle, as shown.

Holding the transparent collar on the syringe, attach syringe to needle luer connection with a firm **clockwise twisting motion** until snug.

Do not touch needle luer opening. This will result in contamination.

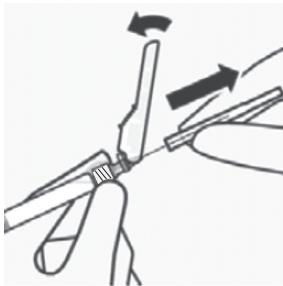


Resuspend microspheres

Fully remove the blister pouch.

Just before injection, shake syringe vigorously again, as some settling will have occurred.

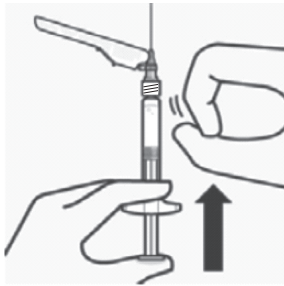
Step 4 Inject Dose



Remove transparent needle protector

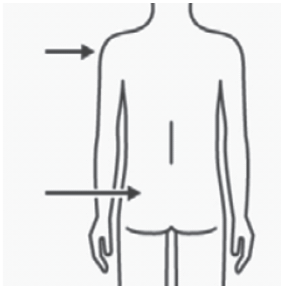
Move the needle safety device back towards the syringe, as shown. Then hold transparent collar on syringe and carefully pull the transparent needle protector straight off.

Do not twist transparent needle protector, as the luer connection may loosen.



Remove air bubble

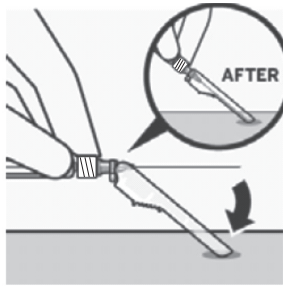
Hold needle upright and tap gently to make any airbubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.



Inject

Immediately inject entire contents of syringe intramuscularly (IM) into the gluteal or deltoid muscle of the patient. Gluteal injection should be made into the upper-outer quadrant of the gluteal area.

Do not administer intravenously.



Secure needle in safety device

Using one hand, place needle safety device at a 45- degree angle on a hard, flat surface. Press down with a firm, quick motion until needle is fully engaged in safety device.

Avoid needle stick injury:

Do not use two hands.

Do not intentionally disengage or mishandle the needle safety device.

Do not attempt to straighten the needle or engage the safety device if the needle is bent or damaged.



Properly dispose of needles

Check to confirm needle safety device is fully engaged. Discard in an approved sharps container.

Also discard the unused needle provided in the dose pack.