

INFORMATION FOR THE HEALTHCARE PROVIDER

Risperidone Teva 25 mg, 37.5 mg and 50 mg

Powder and solvent for preparation of a prolonged-release suspension for intramuscular injection

1. INSTRUCTIONS FOR USE

For deltoid or gluteal intramuscular injection only!

Important information

Risperidone Teva requires close attention to these step-by-step instructions for use to help ensure successful administration.

Use components provided

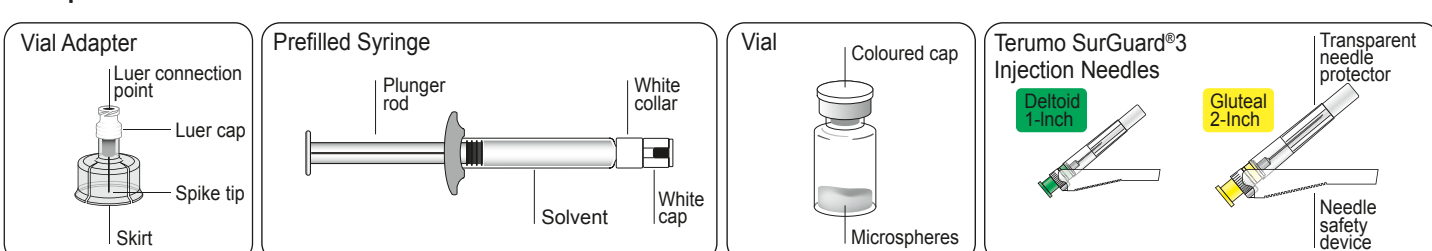
The components in this dose pack are specifically designed for use with Risperidone Teva. Risperidone Teva **must be reconstituted only in the solvent supplied in the dose pack**. Do not substitute ANY components of the dose pack. **Do not store suspension after reconstitution**. Administer dose as soon as possible after reconstitution to avoid settling.

Proper dosing

The entire contents of the vial must be administered to ensure intended dose of risperidone is delivered. **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.

SINGLE-USE DEVICE

Dose pack contents:



Step 1		Assemble components	
Take out dose pack	Connect vial adapter to vial		
Wait 30 minutes Remove 1 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.	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 Peel back the blister pouch and remove the vial adapter by holding between the white luer cap and the skirt. Do not touch spike tip or luer connection point 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, confirmed by an audible "click". Do not place vial adapter on at an angle or solvent may leak upon transfer to the vial.

Connect prefilled syringe to vial adapter			
Swab connection point Keep vial vertical to prevent leakage. Hold base of vial and swab the luer connection point (blue circle) of the vial adapter with an alcohol wipe and allow to dry prior to attaching the syringe. Do not shake. Do not touch luer connection point on vial adapter. This will result in contamination.	Use proper grip Hold by white collar at the tip of the syringe. Do not hold syringe by the glass barrel during assembly.	Remove cap Holding the white collar, snap off the white cap. Do not twist or cut off the white cap. Do not touch syringe tip. This will result in contamination.	Connect syringe to vial adapter Hold vial adapter by skirt to keep stationary. While holding the white collar of the syringe, insert and press the syringe tip into the blue circle of the vial adapter and twist in a clockwise motion to secure the connection of the syringe to the vial adapter (avoid over tightening). Do not hold the glass syringe barrel. This may cause the white collar to loosen or detach.

Step 2		Reconstitute microspheres	
Inject solvent Inject entire amount of solvent from syringe into the vial. Vial contents will now be under pressure. Keep holding the plunger rod down with thumb.	Suspend microspheres in solvent 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 content from the vial into the syringe.	Remove vial adapter Hold white collar on the syringe and unscrew from vial adapter. 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 white 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				
Remove transparent needle protector Move the needle safety device back towards the syringe, as shown. Then hold white 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 bubbles Hold syringe upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod through 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.

2. DOSAGE FORMS AND STRENGTHS

Risperidone Teva is available in dosage strengths of 25 mg, 37.5 mg, and 50 mg risperidone. It is provided in a plastic tray, consisting of one clear glass vial containing the risperidone powder, a prefilled syringe containing 2 mL of solvent, one vial adapter, and two needles for intramuscular injection: a 21G UTW 1-inch needle with needle protection device for deltoid administration and a 20G TW 2-inch needle with needle protection device for gluteal administration.

3. HOW SUPPLIED/STORAGE AND HANDLING

Shelf life

The expiry date of the product is indicated on the packaging materials.
After reconstitution: chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be **used immediately**. If not used immediately, in-use storage times and

conditions prior to use are the responsibility of the user and should normally not be longer than 6 hours at 25°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Storage

The entire dose pack should be stored in the refrigerator (2°C-8°C) and protected from light. Keep out of the sight and reach of children.