INFORMATION FOR THE HEALTHCARE PROVIDER

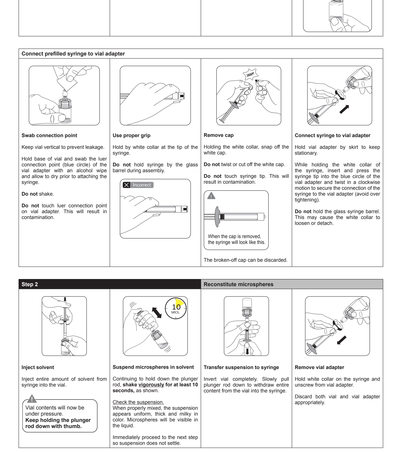
Risperidone Teva
25 mg, 37.5 mg and 50 mg

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

1. INSTRUCTIONS FOR USE
For dermal 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.

SINGLE-USE DEVICE

Dose pack contents:

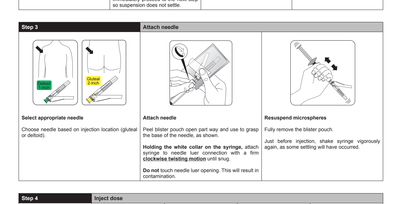


Use components provided
The components in this dose pack are specifically designed for use with risperidone Teva. Risperidone Teva must be reconstituted only in the diluent supplied in the dose pack.
Do not substitute ANY components of the dose pack. Use of other components may compromise product sterility. Use components as supplied.

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 handling and disposal procedures.
These characteristics have been verified for **single use** only. Reuse may compromise safety and subsequent use may adversely affect the integrity of the device or lead to deterioration in performance.

Step 1 — **Assemble components**

Take out dose pack — **Connect vial adapter to vial**



Wait 30 minutes
Remove 1 dose pack from refrigerator and allow to sit at room temperature for at least **30 minutes** before reconstituting.
Do not warm any other way.

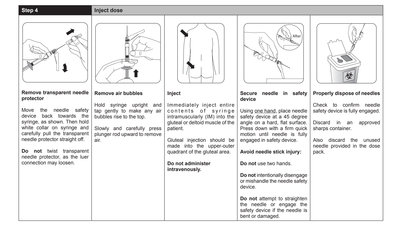
Remove cap from vial
Flip off colored cap from vial.
Wipe top of the gray stopper with an alcohol swab.
Allow to air dry.
Do not remove gray rubber stopper.

Prepare vial adapter
Peel back the blister pouch and remove the vial adapter by holding between the white luer cap and the spike.
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 down with a firm quick motion until the vial adapter is in place, confirmed by an audible "click".
Do not place vial adapter on at an angle. Incorrect alignment may leak upon transfer to the vial.

Step 2 — **Reconstitute microspheres**

Connect prefilled syringe to vial adapter



Swab connection point
Hold syringe upright and swab the connection point (blue cap).

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 slurt 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 with firm and continuous 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 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 — **Inject dose**

Remove transparent needle protector
Move the needle safety lever to the side of 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 luer connection may loosen.

Remove air bubbles
Hold syringe upright and tap gently to make any air bubbles rise.
Slowly and carefully press plunger rod upward to remove air.

Inject
Immediately inject entire contents of syringe intramuscularly 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 lever on a hard surface. Push down with a firm quick motion. Press down with a firm quick motion until needle is fully engaged in safety device.
Avoid needle stick injury:
Do not use fingers.
Do not intentionally disengage or mishandle the needle safety device.
Do not attempt to straighten the needle or disengage 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 respectively.
The pack for the injection is consisting of one dose glass vial containing 1 mL of solvent, one prefilled syringe containing 2 mL of solvent, one vial adapter, and two needles for intramuscular injection - a 21G UTW 1-inch needle with protective cap for deltoid administration and a 20G 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.
Storage conditions: 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 2°C-8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

Disposal
The entire dose pack should be stored in the refrigerator (2°C-8°C) until ready for use.
Keep out of the sight and reach of children.

teva

עלון לצרכן לתרופות המרשם (המטפלים)
רספרידון טבע 25 מ"ג
רספרידון טבע 37.5 מ"ג
רספרידון טבע 50 מ"ג
אבקה לתכשיר לזריקה לשחרור ממושך
לזריקה בשריר בלבד!
Risperidone Teva 25 mg
Risperidone Teva 37.5 mg
Risperidone Teva 50 mg
לקריאה נוספת בעלון מלא זה, עיינו בעלון לרופא - פרק 6 - "מידע נוסף" בעלון לרופא" ובעלון "מידע לרוכשי תרופות".
אם אינכם בטוחים לגבי מצבכם הרפואי, פנו לרופא המטפל שלכם.
אם אינכם בטוחים לגבי אופן הטיפול בכם, פנו לרופא המטפל שלכם.
אם אתם חושדים בתגובה אלרגית, פנו לרופא מיד.
הוראות לשימוש בתכשיר
הוראות אלה מיועדות לרופאים בלבד.
הוראות אלה מיועדות לעזור לכם לוודא הזרקה מוצלחת.
אל תשתמשו בתכשיר אם:
אם אתם חשודים בתגובה אלרגית לרכיבי התכשיר.
אם אתם בהריון, אם אתם מניקות, אם אתם מתכננות הריון.
אם אתם חולים בדיכאון.
אם אתם חולים בהפרעות בתפקוד הכבד.
אם אתם חולים בהפרעות בתפקוד הכליות.
אם אתם חולים בהפרעות בתפקוד הלב.
אם אתם חולים בסוכרת.
אם אתם חולים בפרכוסים.
אם אתם חולים בפרקינסון.
אם אתם חולים בנוירולפטיות ממאירה (Neuroleptic Malignant Syndrome) - מצב רפואי חמור הגורם לנוקשות בשרירים, חום גבוה, הזעה, ירידה ברמת ההכרה ועליה ברמת אנזים בדם (Creatine Phosphokinase).
אם אתם חולים בלוקמיה.
אם אתם חולים בגידולים תלויי-פרולקטין.
אם אתם חולים בגידול בלבלב.
אם אתם חולים בגידול בבלוטת יותרת הכליה.
אם אתם חולים בגידול בבלוטת יותרת המוח.
אם אתם חולים בגידול בבלוטת פרתירואיד.
אם אתם חולים בגידול בבלוטת הרוק.
אם אתם חולים בגידול בבלוטת הזיע.
אם אתם חולים בגידול בבלוטת הדמעות.
**אם אתם חולים בגידול בבלוטת הכיח