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

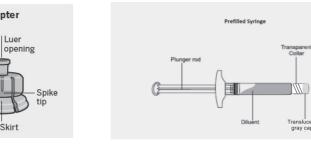
after reconstitution to avoid settling.

Proper dosing

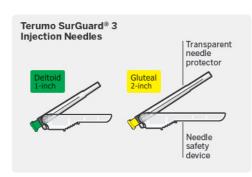
The entire contents of the vial must be administered to ensure intended dose of risperidone for extended-release injectable suspension is delivered.

Contents



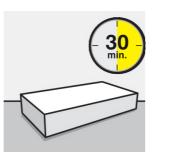






Dose Pack

Take out dose pack



Step 1 Assemble Components

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.

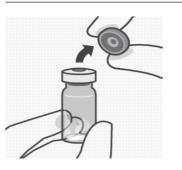
<u>alcohol swab.</u>

cap from vial.

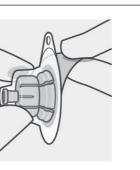
Allow to air dry.

Do not remove gray rubber stopper.

Connect vial adapter to vial



Remove cap from vial. Flip off colored **Prepare vial adapter.** Hold sterile blister Wipe top of the gray stopper with an



as shown. Peel back and remove paper

Do not remove vial adapter from

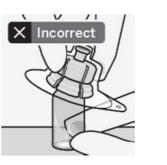
Do not touch spike tip at any time. This will result in contamination.



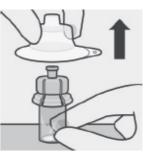
Connect vial adapter to vial

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



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.

vial adapter. This will result in contamination.

Do not touch exposed luer opening on



Use proper grip

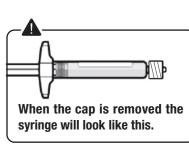
Hold by transparent collar at the tip of the syringe. **Do not** hold syringe by the glass barrel during assembly.

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

Remove cap

counter clockwise.

TRANSLUCENT GRAY CAP.

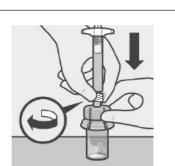


Holding the transparent collar, unscrew

the translucent gray cap by turning it

DO NOT SNAP OR CUT OFF THE

The unscrewed cap can be discarded.



Connect syringe to vial adapter Hold vial adapter by skirt to keep

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.

or lead to deterioration in performance. may adversely affect the integrity of the device re-process the device for subsequent re-use verified for single use only. Any attempt to as intended. These characteristics have been specific material characteristics to perform

IMPORTANT RESOURCES Do not reuse. Medical devices require SINGLE-DOSE DEVICE

suspension requires close attention to these

Nanomi B.V., a Lupin Group Company, 7575 EJ, Oldenzaal,

Made in France

at 1-800-399-2561. Pharmaceuticals Inc. For additional information, call Lupin

healthcare professional. Each injection should be administered by a nsure successful administration. PRIOR TO USE injection only

PLEASE READ COMPLETE INSTRUCTIONS step-by-step Instructions for Use to help For deltoid or gluteal intramuscular Risperidone for extended-release injectable

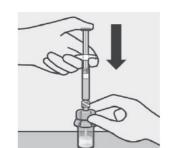
15.5 mg/vial and 5.75 RISPERIDONE for extended-release injectable suspension, 25 mg/vial, Instructions for Use

Manufactured for: The Netherlands

February 2025 ID#: 005U9800200

Distributed by: Lupin Pharmaceuticals, Inc. Naples, FL 34108

United States



Inject diluent Inject entire amount of diluent from syringe into the vial.

Vial contents will now be under Keep holding the plunger rod down with thumb.



Check the suspension.

appears uniform, thick and milky in color.

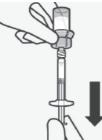
> Immediately proceed to the next step so suspension does not settle.



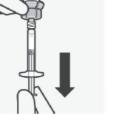
Suspend microspheres in diluent Continuing to hold down the plunger rod, **shake vigorously for at least** 10 seconds, as shown.

When properly mixed, the suspension

Microspheres will be visible in the liquid.



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

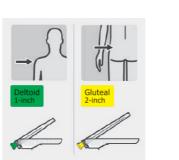




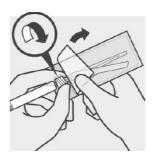
Remove vial adapter Hold transparent collar on the syringe and unscrew from vial adapter.

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).



Peel blister pouch open part way and

use to grasp the base of the needle, Holding the transparent collar on

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

will result in contamination.

Do not touch needle luer opening. This



Resuspend microspheres Fully remove the blister pouch.

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



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.

Step 4 Inject Dose

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



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.



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





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:

Secure needle in safety device

Do not use two hands. Do not intentionally disengage or

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



is fully engaged. Discard in an approved sharps container. Also discard the unused needle provided

in the dose pack.

mishandle the needle safety device.



