For deltoid or gluteal intramuscular injection only

Instructions for use
RISPERDAL® CONSTA® requires close attention to these step-by-step Instructions for Use to help ensure successful administration.

SINGLE-USE DEVICE
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 Information

Use components provided
The components in this dose pack are specifically designed for use with RISPERDAL® CONSTA®. RISPERDAL® CONSTA® 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 RISPERDAL® CONSTA® is delivered.

Dose pack contents

**West-Medimop Vial Adapter®**
- Luer opening
- Spike tip
- Skirt

**Prefilled Syringe**
- Plunger rod
- Diluent
- White collar
- White cap

**Vial**
- Colored cap
- Microspheres

**Terumo SurGuard® 3 Injection Needles**
- Transparent needle protector
- Needle safety device
- Deltoid 1-inch
- Gluteal 2-inch
Step 1 Assemble components

Take out dose pack

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

Wait 30 minutes

Remove cap from vial

Flip off colored cap from vial.

Wipe top of the grey stopper with an alcohol swab. Allow to air dry.

Do not remove grey 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 grey 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.
Step 1  Assemble components (continued)

Connect prefilled syringe to vial adapter

Remove sterile blister

Remove vial adapter from sterile blister only when you are ready to remove the white 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 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.

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

Do not hold the glass syringe barrel. This may cause the white 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.
**Step 2**  
**Reconstitute microspheres**

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

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

**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 white 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.

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**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 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 needle upright and tap gently to make any air bubbles 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.

Step 4  Inject dose (continued)

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.

IMPORTANT RESOURCES
For additional information, visit risperdalconsta.com or call Janssen Pharmaceuticals, Inc. at 1-800-526-7736, 9am-8pm (ET), Monday through Friday, and 9am-5pm (ET), Saturday and Sunday.

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