

INSTRUCTIONS FOR USE

PERSERIS™ (risperidone) for extended-release injectable suspension

90 mg or 120 mg, sterile, single dose

**For abdominal subcutaneous injection only.
Do not administer by any other route.**

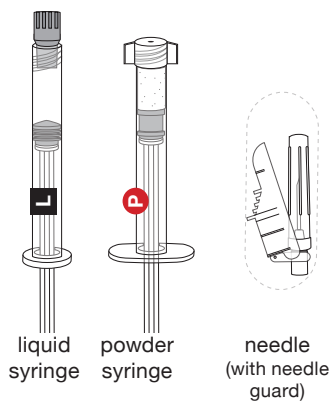
Additional information, including an instructional video, are available at perserishcp.com. The additional information has not been evaluated or approved by the FDA.

IMPORTANT INFORMATION:

- To be administered by a healthcare professional only.
- Please read the instructions carefully before handling this product.
- Allow package to come to room temperature for at least 15 minutes prior to preparation.
- Only prepare medication when you are ready to administer the dose.
- As a universal precaution, always wear gloves.

1 CHECK CONTENTS

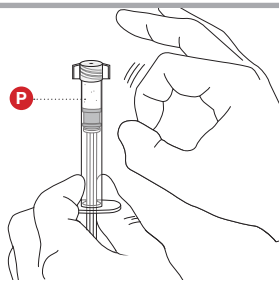
- One **Liquid Syringe** (**L**) pre-filled with the delivery system - Inspect liquid solution for foreign particles. This is the syringe you will use to inject the patient.
- One **Powder Syringe** (**P**) prefilled with Risperidone powder - Inspect syringe for consistency of powder color and for foreign particles.
- One sterile 18-gauge, 5/8 inch safety needle
- Parenteral drug products should always be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.



2 TAP POWDER SYRINGE

- Hold the **Powder Syringe** upright and tap the barrel of the syringe to dislodge the packed powder.

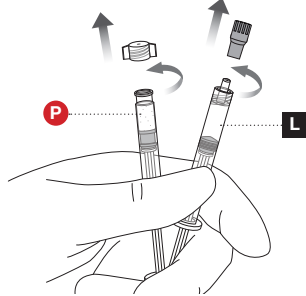
NOTE Powder can become packed during shipping.



3 UNCAP LIQUID AND POWDER SYRINGES

- Remove the cap from the **Liquid Syringe**, then remove the cap from the **Powder Syringe**.

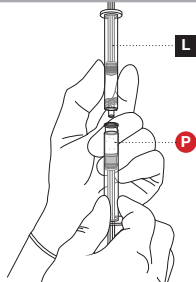
TIP Holding both syringes in your non-dominant hand can help with this step.



4 CONNECT THE SYRINGES

- Place the **Liquid Syringe** on top of the **Powder Syringe** (to prevent powder spillage) and connect the syringes by twisting approximately 3/4 turn. Do not over tighten.

CAUTION Keep your fingers off the plungers during this step to avoid spillage of the medication.



5 MIX THE PRODUCT

WARNING Failure to fully mix the medication could result in incorrect dosage.

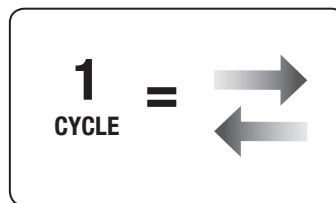
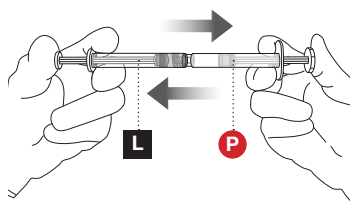
Premixing:

- Transfer the contents of the **Liquid Syringe** into the **Powder Syringe**.
- Gently push the **Powder Syringe** plunger until you feel resistance (to wet powder and avoid compacting).
- Repeat this gentle back-and-forth process for **5 Cycles**.

Complete mixing:

- Continue mixing the syringes for an additional **55 Cycles**.
- This mixing can be more vigorous than when pre-mixing.

TIP Graphic to the right illustrates a correct full cycle.

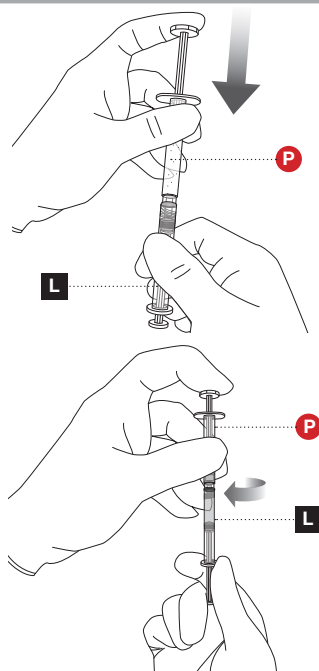


6 PREPARE INJECTION SYRINGE

WARNING Failure to aspirate the liquid from the **Powder Syringe** may result in incorrect dosage.

- First, transfer all contents into the **Liquid Syringe**.
- Next, perform the following actions **SIMULTANEOUSLY**:
 - ▶ maintain slight pressure on the **Powder Syringe** plunger and
 - ▶ pull back **gently** on the **Liquid Syringe** plunger while twisting the syringes apart.
- Finally, attach the safety needle by twisting until finger tight.

NOTE Check that medication is uniform in color and free from foreign particles.



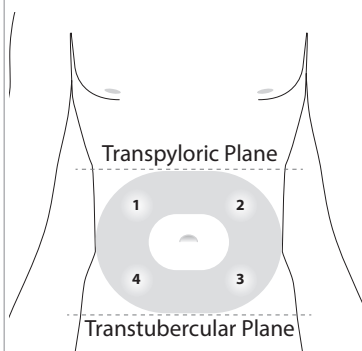
Turn the Page

PERSERIS™
Instructions for Use

7 PREPARE THE ABDOMINAL INJECTION SITE

- Choose an injection site on the abdomen with adequate subcutaneous tissue that is free of skin conditions (e.g. nodules, lesions, excessive pigment). It is recommended that the patient is in the supine position.
- **Do not** inject into an area where the skin is irritated, reddened, bruised, infected or scarred in any way.
- Clean the injection site well with an alcohol pad.

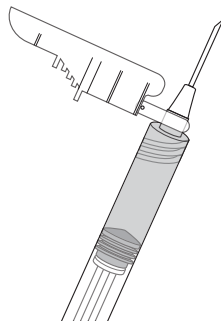
TIP To help minimize irritation, rotate injection sites following a pattern similar to the illustration.



8 REMOVE EXCESS AIR FROM SYRINGE

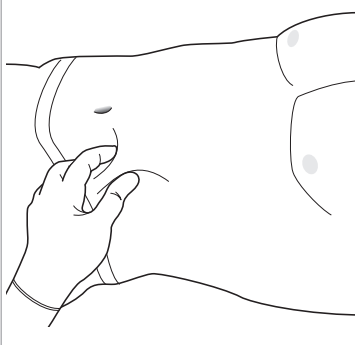
- Hold the syringe upright for several seconds to allow air bubbles to rise.
- Remove needle cover and slowly depress the plunger to push out the excess air from the syringe.
- If medication is seen at the needle tip, pull back slightly on the plunger to prevent medication spillage.

NOTE Due to the viscous nature of the medication, bubbles will not rise as quickly as those in an aqueous solution.



9 PINCH INJECTION SITE

- Pinch the skin around the injection area. Be sure to pinch enough skin to accommodate the size of the needle. Lift the adipose tissue from the underlying muscle to prevent accidental intramuscular injection.

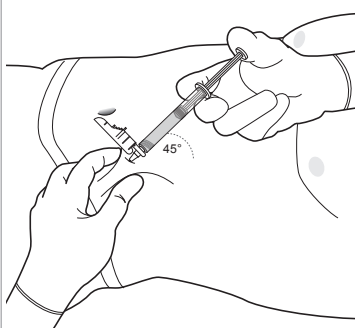


10 INJECT THE MEDICATION

- Insert needle fully into the subcutaneous tissue.
- Inject the medication slow and steady.

CAUTION PERSERIS™ is for subcutaneous administration only. Do not inject by any other route.

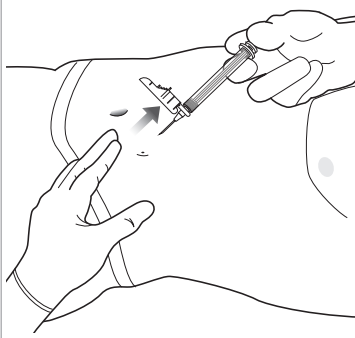
NOTE Actual angle of injection will depend on the amount of subcutaneous tissue.



11 WITHDRAW NEEDLE

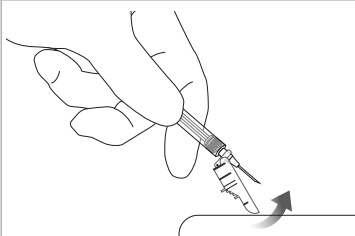
- Withdraw the needle at the same angle used for insertion and release pinched skin.

CAUTION Do not rub the injection area after the injection. If there is bleeding, apply a gauze pad or bandage but use minimal pressure.



12 LOCK THE NEEDLE GUARD AND DISPOSE OF SYRINGE

- Lock the needle guard into place by pushing it against a hard surface such as a table.
- Dispose of all syringe components in a secure sharps disposal container.



13 INSTRUCT THE PATIENT

- Advise the patient that they may have a lump for several weeks that will decrease in size over time. It is important that the patient not rub or massage the injection site and to be aware of the placement of any belts or clothing waistbands.



FREQUENTLY ASKED QUESTIONS

Q What is the mixture supposed to look like?

A When fully mixed, the product should be a cloudy suspension that is uniform in color. It can vary from white to yellow-green in color. If you see any clear areas in the mixture, continue to mix until the distribution of the color is uniform.

Q Why is it important to put the liquid syringe on top?

A The liquid is viscous and will not fall out when placing on top. However, powder may be lost if the powder syringe is inverted, which could affect the ultimate dosage.

Q What do I do if there is residual left in the powder syringe?

A A small ring of residual powder may be observed in the end of the powder syringe barrel after mixing. This is normal. If you have followed the instructions carefully and the rest of the mixture is a cloudy suspension that is uniform in color, proceed with the injection.

Q What do I do if a foreign particle is found in either of the syringes?

A Do not use if you suspect foreign particles in either of the syringes

Q How soon must I inject after mixing PERSERIS™?

A This product should be used immediately following preparation.

Q Can I inject into the arm or leg?

A This injection is only approved for injection into the abdomen.

Q How do I get rid of large air gaps?

A Small bubbles, also known as champagne bubbles, are not a problem and common with this medication. Large air gaps, however, can be minimized by pulling back on the plunger rod to pop air bubbles prior to expelling the air very slowly. Air should be expelled very carefully to avoid loss of medication.

Q Should I massage or put my finger on the injection site following the injection?

A It is not advisable to palpate or massage the area following the injection.

Q Will the deposit be palpable?

A Depending on the patient's subcutaneous tissue, the deposit may be more or less palpable. Patients should be advised that a bump may be palpable (decreasing in size) for several weeks.

Manufactured for: Indivior Inc.,
North Chesterfield, VA 23235.

Powder syringe manufactured by Patheon
Manufacturing Services, Greenville, NC 27834.

Liquid syringe manufactured by AMRI Global,
Burlington, MA 01803.

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