PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Risperidone Teva 25 mg
Risperidone Teva 37.5 mg
Risperidone Teva 50 mg

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

Composition:
Each vial of Risperidone Teva 25 mg contains:
Risperidone 25 mg
Each vial of Risperidone Teva 37.5 mg contains:
Risperidone 37.5 mg
Each vial of Risperidone Teva 50 mg contains:
Risperidone 50 mg

For information regarding inactive ingredients and allergens see section 6 – "Additional information" and section 2 – "Important information about some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine.
If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Warning: increased mortality in elderly patients who suffer from psychosis-related dementia.
Elderly patients with psychosis-related dementia who are treated with antipsychotics are at an increased risk of death. Risperidone Teva is not approved for patients with psychosis-related dementia.

1. WHAT IS THE MEDICINE INTENDED FOR?

Risperidone Teva in intended for the treatment of schizophrenia and schizoaffective disorders.
Risperidone Teva is intended as a maintenance monotherapy for bipolar disorder, in order to delay the occurrence of mood episodes.
Risperidone Teva is intended as an adjunctive maintenance treatment, in order to delay the occurrence of mood episodes in patients with frequent recurrent attacks of bipolar disorder.
Therapeutic class: atypical antipsychotics.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:
You are sensitive (allergic) to the active ingredient (risperidone) or to its metabolite (paliperidone) or to any of the additional ingredients this medicine contains (see section 6). Hypersensitivity reactions, including anaphylactic reaction and angioedema, have been reported in patients treated with risperidone and paliperidone.

Special warnings regarding the use of the medicine:
- Studies in elderly patients suffering from dementia have shown that taking risperidone alone or with furosemide is associated with a higher incidence of death. Tell the doctor if you are taking furosemide (a medicine for treatment of high blood pressure, certain heart problems or edema in the body due to fluid retention).
- Risperidone Teva is not approved for use in elderly people with dementia. In elderly patients suffering from dementia, cases of sudden change in the mental state, sudden weakness or numbness sensation in the face, arms or legs, especially on one side of the body, or instances of unclear speech have been observed. If any of these occur, even for a short period of time, seek medical assistance immediately.
- A state of confusion, reduced consciousness, high fever or muscle stiffness may occur while using the medicine (a condition called neuroleptic malignant syndrome). Additional signs may include increased creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. If this effect occurs, refer to a doctor immediately and inform him that you are taking Risperidone Teva.
- Prolonged use of Risperidone Teva may cause irreversible involuntary twitching in the face (tardive dyskinesia). If this effect occurs, refer to the doctor. This effect may occur even after stopping treatment.
- Risperidone may cause weight gain. Significant weight gain may adversely affect your health. The doctor must monitor your weight regularly.
- Diabetes, hyperglycemia (high blood sugar levels) or worsening of pre-existing diabetes have been observed in patients taking risperidone. The doctor must monitor the appearance of signs of hyperglycemia. The doctor must monitor sugar levels regularly **in each patient** receiving Risperidone Teva.
- Refer to the doctor if you suffer from increased thirst or increased urination.
- Risperidone Teva may cause a high level of prolactin in the blood (hyperprolactinemia). Refer to the doctor if you have any of the following symptoms: in women – lack of menstrual period or discharge of milk from the breasts, in men – erectile dysfunction or breast swelling.
- During surgery for cataract (an eye disease manifested by cloudiness of the eye lens), the pupil of the eye (the black circle in the middle of the eye) may not increase to the desired size. Also, the iris of the eye (the colored part of the eye) may become floppy during surgery, which may lead to eye damage. If you are planning to undergo eye surgery, tell your doctor that you are taking this medicine.
- If you have never taken risperidone in any other dosage form, start with oral risperidone before starting treatment with Risperidone Teva. Even if you have previously been treated with oral risperidone, in rare cases, an allergic reaction occurs after receiving a risperidone injection. Seek immediate medical assistance if you experience rash, swelling of the throat, itch or breathing problems, since these may be the signs of an acute allergic reaction.

Before treatment with Risperidone Teva, inform the doctor if:
- You suffer or have previously suffered from impaired function of the heart, particularly heart rhythm disorders, abnormal electrical activity of the heart or if you are taking medicines that change the electrical activity of the heart – use Risperidone Teva with caution and only after consulting the doctor.
- You are prone to low blood pressure, you are taking medicines for treatment of high blood pressure, since low blood pressure may result from concomitant use of Risperidone Teva and medicines for lowering blood pressure.
- You or someone in your family suffers or has previously suffered from blood clots. Blood clots in the lungs and legs have been observed in patients taking risperidone. Blood clots in the lungs may be fatal.
- You have previously suffered from low white blood cell count (even if caused by the use of other medicines), since very low levels of white blood cells (required to protect against infections) has been observed rarely in patients taking risperidone. The doctor may perform blood tests to check white blood cell levels.
- You suffer from a heart or vascular disease, diabetes, Parkinson's, dementia associated with Lewy bodies or epilepsy. Medical supervision may be required while you are receiving Risperidone Teva, and the dosage or treatment may need to be adjusted.
- You have risk factors for stroke, such as high blood pressure, heart and vascular problems or problems with blood flow in the brain.
- You are a man and have ever suffered from prolonged or painful erection.
- You suffer from problems regulating body temperature or from overheating.
- You suffer from liver or kidney problems.
- You suffer from abnormally high levels of the hormone prolactin in the blood or if you have a prolactin-dependent cancerous tumor.
- You have ever suffered from involuntary movements of the tongue, mouth or face.
- You are at risk of aspiration pneumonia.

Children and adolescents:
Risperidone Teva has not been tested in clinical trials in children and adolescents under 18 years of age.

Drug interactions:
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:
- Medicines that reduce the ability to react (sedatives, narcotic analgesics, certain antihistamines – certain medicines for treatment of allergy, certain antidepressants). Risperidone Teva may enhance their effect.
- Medicines for treatment of Parkinson's disease such as dopamine agonists (e.g., levodopa).
- Medicines for the treatment of high blood pressure. Taking them together with risperidone may cause the blood pressure to drop too low.
- Medicines that may change the electrical activity of the heart, such as (but not limited to) medicines for the treatment of malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, diuretic preparations or other medicines that affect the levels of salts in the body (sodium, potassium, magnesium).
- Clozapine.
- Phenytoin, rifampicin and phenobarbital.
- Carbamazepine (a medicine used mainly for treatment of epilepsy or of attacks of severe pain in the face (trigeminal neuralgia)). This medicine may reduce the level of Risperidone Teva in the blood.
- Furosemide (see section "Special warnings regarding the use of the medicine").
- Methylphenidate, a medicine for treatment of attention deficit hyperactivity disorder (ADHD). Extrapyramidal symptoms (dystonia and dyskinesia) have been reported in patients taking methylphenidate and risperidone, when there was a change in the dosage of one of these medicines.
- Quinidine (a medicine for treatment of certain heart problems).
- Antidepressants, such as paroxetine, fluoxetine, tricyclic antidepressants.
- Beta blockers (for treatment of high blood pressure).
- Phenothiazines (such as medicines for treatment of psychosis or for sedation).
- Cimetidine, ranitidine (medicines for reducing stomach acidity).
- Itraconazole and ketoconazole (for treatment of fungal infections).
- Certain medicines for treatment of HIV/AIDS, such as ritonavir.
- Verapamil (for treatment of high blood pressure and/or abnormal heart rate).
- Sertraline and fluvoxamine (for treatment of depression and other psychiatric disorders). If you start or stop taking these medicines, you may need a different dosage of risperidone.

Use of the medicine and alcohol consumption:
Do not drink wine or other alcoholic beverages during treatment with the medicine, the medicine may enhance the effect of alcohol.

Pregnancy, breastfeeding and fertility:
Pregnancy:
If you are pregnant or planning to become pregnant, consult the doctor who will decide whether you are allowed to use Risperidone Teva. For your information, the use of Risperidone Teva may cause extrapyramidal symptoms and/or withdrawal symptoms in the newborn.
Breastfeeding:
If you are breastfeeding, consult the doctor before using the medicine. Breastfeeding mothers who are being treated with the medicine need to check whether their baby develops tremor, muscle stiffness and/or weakness, sleepiness, irritability, respiratory distress or difficulty feeding. If the baby suffers from these effects, seek medical assistance.
Fertility:
Risperidone Teva may cause an increase in the levels of the hormone prolactin, which may affect fertility (see section 4 "Side effects"). If there is an effect on fertility, this effect is reversible.

Driving and operating machinery:
The medicine may affect alertness or the ability to drive. Do not drive or operate dangerous machinery while using the medicine before the doctor assesses the effect of the medicine on you.

Important information about some of the ingredients of the medicine:
Risperidone Teva contains less than 1 mmol (23 mg) of sodium per 1 ml of suspension after reconstitution, and is therefore considered "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined only by the doctor.
Risperidone Teva is given by intramuscular injection to the buttock or to the arm muscle every two weeks by a healthcare professional. Injections should be alternated between the right and left sides of the body. Do not inject intravenously.
The generally accepted dosage is 25 mg as an intramuscular injection, every two weeks. A higher dosage (37.5 mg or 50 mg) may be required.
The doctor may also instruct you to take risperidone tablets for the first three weeks after administering the first injection.
Do not exceed the recommended dose.
If you accidentally took a higher dosage:
An overdose is less likely with risperidone injections than with oral risperidone (such as pills or solution).
In cases of overdose, one or more of the following signs may occur: decreased consciousness, drowsiness, sleepiness, excessive tremor, muscle stiffness, increased heart rate and low blood pressure.
There have been reports of cases of abnormal electrical conduction in the heart (prolongation of the QT interval) and convulsions. Cases of overdose can also occur if you are taking additional medicines with risperidone.
If you experience any of the symptoms described or if a child accidentally took the medicine, refer to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.
If you forgot to take the medicine:
If you forgot to take this medicine at the appointed time, consult the doctor or nurse at the clinic where you are being treated.
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine except in consultation with the doctor and in a controlled manner.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Risperidone Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Refer to a doctor immediately if:
- You experience a blood clot in the veins, particularly in the legs (symptoms include swelling, pain and redness in the leg), which can travel through the blood vessels to the lungs and cause chest pain and breathing difficulties. If you notice any of these symptoms, seek medical assistance immediately.
- You suffer from dementia and you experience a sudden change in your mental state or sudden weakness or a sensation of numbness in the face, arms or legs, especially in one side of the body, or incidents of unclear speech, even if for a short period of time. These may be signs of a stroke. If any of these occur, seek medical assistance immediately.
- You experience fever, muscle stiffness, sweating or a decrease in the level of consciousness (a disorder called: neuroleptic malignant syndrome). You may require immediate medical treatment.
- You are a man and you experience prolonged or painful erection. This phenomenon is called priapism. You may need immediate medical treatment.
- You experience involuntary rhythmic movements of the tongue, mouth or face. You may need to discontinue the use of the medicine.
- You experience an acute allergic reaction characterized by fever, swelling of the mouth, face, lips or tongue, shortness of breath, itch, skin rash or a decrease in blood pressure. Even if you have previously taken risperidone orally without suffering from an allergic reaction, in rare cases, an allergic reaction may occur after receiving an injection of risperidone.

Additional side effects
Very common side effects – effects that occur in more than 1 user out of 10:
- Common cold symptoms
- Difficulty falling asleep or difficulty sleeping continuously
- Depression, anxiety
- Parkinsonism which is manifested by impaired or slow movement, sensation of muscle stiffness or muscle contractions and sometimes even a sensation of freezing in movement and a need to restart the movement, slow shuffling walk, tremor while at rest, increased salivation and/or increased drooling and loss of facial expression
- Headache

Common side effects – effects that occur in 1-10 users out of 100:
- Pneumonia, inflammation of the bronchi (bronchitis), sinus infection, urinary tract infection, a flu-like illness
- Anemia
- Risperidone Teva may increase the levels of the hormone prolactin, which can be seen in blood tests (which can, but not necessarily, cause symptoms). The symptoms of high prolactin levels include: in women – lack of menstrual period or discharge of milk from the breasts, in men – erectile dysfunction or breast swelling
- High blood sugar levels, weight gain, weight loss, decrease or increase in appetite
- Sleeping problems, nervousness, decreased libido, restlessness, feeling sleepy or low alertness
- Dystonia – an effect that includes slow or continuous involuntary contraction of the muscles. Although this effect can involve any part of the body (and can be manifested by abnormal posture), facial muscles will usually be affected. The effect includes abnormal movements of the eyes, mouth, tongue or jaw
- Dizziness
- Dyskinesia – involuntary muscle movement which may include repetitive movements, twitching or writhing
- Tremor
- Blurred vision
- Rapid heartbeat
- Low blood pressure, high blood pressure
- Shortness of breath, sore throat, cough and nasal congestion
- Abdominal pain or abdominal discomfort, vomiting, infection of the gastrointestinal system, constipation, diarrhea, indigestion, dry mouth and toothache
- Rash
- Muscle cramps, muscle or bone pain, back pain, joint pain
- Urinary incontinence (inability to hold in)
- Erectile dysfunction
- Lack of menstrual period
- Leakage of milk from the breasts
- Swelling in the body, hands or legs, fever, chest discomfort, weakness, tiredness
- Pain
- Injection site reaction including itch, pain or swelling
- Increased levels of liver enzymes in the blood
- Falls

Uncommon side effects – effects that occur in 1-10 users out of 1,000:
- Respiratory tract infection, bladder infection, ear infection, eye infection, tonsillitis, fungal infection of the nails, skin infection, an infection limited to a certain area of the skin or part of the body, viral infection, skin infection as a result of exposure to mites, subcutaneous abscess
- Reduced white blood cell count, reduced platelet level (blood cells that aid in stopping bleeding), reduced red blood cell count
- An allergic reaction
- Presence of sugar in the urine, diabetes or worsening of diabetes
- Loss of appetite which may lead to malnutrition and weight loss
- Increased levels of triglycerides and/or cholesterol (lipids) in the blood
- Elated mood (mania), confusion, difficulty reaching orgasm, nightmares
- Tardive dyskinesia – involuntary movements and/or twitching of the face, tongue or other parts of the body. If you have involuntary and rhythmic movements of the tongue, mouth and face, refer to the doctor immediately. The doctor may instruct you to stop the treatment with Risperidone Teva
- Sudden cessation of blood flow to the brain (stroke or mini-stroke)
- Loss of consciousness, convulsions, fainting
- Uncontrollable urge to move certain body parts, balance disorders, abnormal coordination, dizziness when standing up, attention disorders, speech problems, loss of or problems with the sense of taste, reduced skin sensitivity to pain and touch, sensation of tingling or numbness of the skin
- Eye infection, conjunctivitis, dryness in the eyes, excessive tearing, redness of the eyes
- Sensation of dizziness (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (irregular heart rate), an interruption in the conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT interval of the heart, slow heartbeat, abnormal cardiac electrical tracing test result (electrocardiogram/ECG), awareness of abnormal heartbeats (palpitations)
- Low blood pressure upon standing up (as a result, certain people taking Risperidone Teva may feel weakness, dizziness, or may faint upon sudden change to a standing or sitting position)
- Rapid and shallow breathing, congestion in the respiratory tract, wheezing, nosebleed
- Stool incontinence (inability to hold in), difficulty swallowing, excessive gas in the gastrointestinal system
- Itch, hair loss (alopecia), eczema, dry skin, redness in the skin, skin discoloration, acne, dandruff
- Increased CPK (creatine phosphokinase) levels in the blood, an enzyme released as a result of muscle injury or damage
- Joint stiffness, swelling of the joints, muscle weakness, neck pain
- Frequent passing of urine, inability to urinate, pain while urinating
- Ejaculation disorders
- Delayed menstruation, lack of menstrual period or any other disorder related to the menstrual period
- Breast development in men, sexual dysfunction, discomfort in the breasts, vaginal discharge
- Swelling of the face, mouth, eyes or lips
- Chills, increased body temperature
- Change in the way you walk
- Feeling of thirst, general malaise, low mood
- Skin hardening
- Increased liver enzyme levels in the blood
- Pain upon receiving treatment

Rare side effects – effects that occur in 1-10 users out of 10,000:
- Reduced levels of white blood cells that are responsible for protecting against infections
- Abnormal secretion of the hormone that regulates urine volume
- Low blood sugar levels
- Excessive drinking of water
- Lack of emotion
- Neuroleptic malignant syndrome: confusion, reduced or lack of consciousness, high fever and severe muscle stiffness
- Low level of consciousness/awareness
- Head tremor
- Disturbance in the movement of the eyes, eye rolling, oversensitivity of the eyes to light
- Abnormal heart rate
- Blood clots in the legs, blood clots in the lungs
- Breathing difficulties (inability to breathe) while sleeping
- Pneumonia due to food aspiration, lung congestion
- Explosive lung sounds, voice problems, problems in the respiratory tract
- Inflammation of the pancreas (pancreatitis), intestinal obstruction
- Skin rash related to the use of the medicine, hives (allergic skin reaction), thickening of the skin, skin problems, skin bruises
- Breakdown of muscle fibers and muscle pain
- Posture problems
- Enlarged breasts, discharge from the breasts
- Reduced body temperature, feeling of discomfort
- Yellowing of the skin and the eyes (jaundice)

Very rare side effects – effects that occur in less than one user out of 10,000:
- Life-threatening complications as a result of uncontrolled diabetes
- Severe allergic reaction with swelling which may involve the throat and lead to breathing difficulties
- In very rare cases, an allergic reaction may occur after receiving a risperidone injection, even in patients who have been treated with oral risperidone without an allergic reaction. **Seek medical treatment immediately if you suffer from rash, swelling of the throat, itch or breathing difficulties, as these are signs of a severe allergic reaction.**
- Lack of muscle motility in the gastrointestinal system that causes blockage
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) may occur if you have used Risperidone Teva during the last three months. If you have to undergo cataract surgery, tell the doctor if you are taking Risperidone Teva or if you have taken the medicine in the last three months

Side effects with unknown frequency (effects whose frequency has not yet been determined):
- A dangerous reduction in the number of white blood cells of the type needed to protect against infections
- Acute allergic reaction characterized by fever, swelling of the mouth, face, lips or tongue, shortness of breath, itch, skin rash and sometimes a drop in blood pressure
- Extremely excessive drinking of water that endangers the body
- Increased insulin levels in the blood (a hormone that regulates sugar levels in the body)
- Problem in blood vessels in the brain
- Lack of reaction to stimuli
- Coma as a result of uncontrolled diabetes
- Sudden loss of vision or blindness
- Glaucoma (increased intraocular pressure), eyelid margin crusting
- Increased heartbeats when switching to a standing position
- Flushing, swelling of the tongue
- Very hard stool
- Cracked lips
- Prolonged erection that may require surgical intervention
- Swelling of glands in the chest
- Sensation of coldness in the legs and hands
- Symptoms of medicine withdrawal
- Inflammation of the bowel
- Diabetes, worsening of pre-existing diabetes
- Sleepwalking
- Stevens-Johnson syndrome
- Toxic epidermal necrolysis (TEN)
- Ketoacidosis in patients with glucose metabolism disturbance
- Catatonia
- Thrombotic thrombocytopenic purpura
- Severe reactions at the injection site including abscess, cellulitis, cyst, hematoma, necrosis, lumps and ulcer
- Anaphylactic reaction
- Extrapyramidal symptoms (dystonia and dyskinesia) have been reported in patients taking methylphenidate and risperidone, when there was a change in the dosage of one of these medicines

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Storage conditions: store refrigerated (2°C - 8°C) and protect from light.
Storage conditions after reconstitution: Use immediately after reconstitution.
The chemical and physical stability after reconstitution 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, storage times and conditions prior to use are the responsibility of the user, and should normally not exceed 6 hours at 25°C, unless reconstitution has been carried out in controlled and validated aseptic conditions.

6. ADDITIONAL INFORMATION:

In addition to the active ingredient the medicine also contains:
Vial: poly(D,L-lactide-co-glycolide)
Reconstitution solvent:
Carmellose sodium, sodium chloride, disodium hydrogen phosphate dihydrate, citric acid anhydrous, polysorbate 20, sodium hydroxide, water for injection.
What does the medicine look like and what are the contents of the package?
A vial with powder (contains the active ingredient risperidone): the powder is white to off-white and is free of foreign particles.
A syringe with solvent for reconstitution: the solvent is a clear, colorless solution, free of foreign particles.
The kit contains:
- A glass vial with powder. The vial is sealed with a gray rubber stopper with a pink, green or blue aluminum cap on top of it, for Risperidone Teva 25 mg, 37.5 mg and 50 mg respectively
- Glass syringe that contains 2 ml reconstitution solvent
- A reconstitution vial adapter
- Green safety needle for injection into the shoulder muscle
- Yellow safety needle for injection into the buttock muscle

Quantity in the package: 1, 2 or 5 kits per package.
Not all package sizes may be marketed.

Name and address of the manufacturer:
Pharmathen International SA, Rodopi, Greece.
Name and address of the license holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:
Risperidone Teva 25 mg: 173.17.36592.99
Risperidone Teva 37.5 mg: 173.18.36593.99
Risperidone Teva 50 mg: 173.19.36594.99

Revised in March 2025.

You may contact the license holder for a printed leaflet in English at: Tevacare@med-trix.com or by telephone: 1-800-805-005

RISP TEVA SYRVIAL PIL MW0325

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!

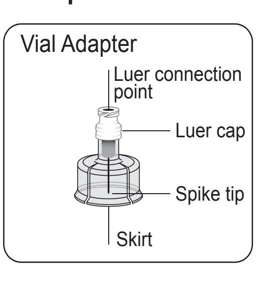
Important information
Risperidone Teva requires close attention to these step-by-step instructions for use to help ensure successful administration.

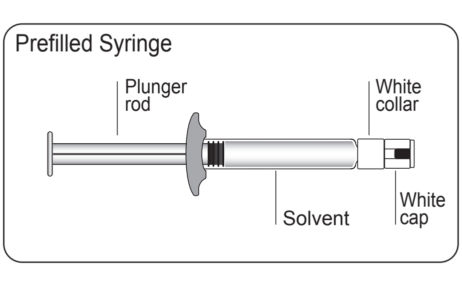
Use components provided
The components in this dose pack are specifically designed for use with Risperidone Teva. Risperidone Teva **must be reconstituted only in the solvent supplied in the dose pack**.
Do not substitute ANY components of the dose pack.
Do not store suspension after reconstitution
Administer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

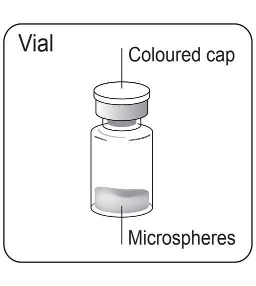
Proper dosing
The entire contents of the vial must be administered to ensure intended dose of risperidone is delivered.
Do not reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for **single use only**. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

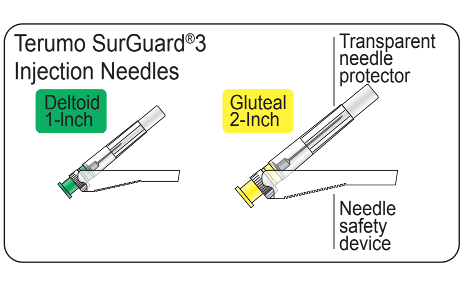
SINGLE-USE DEVICE

Dose pack contents:



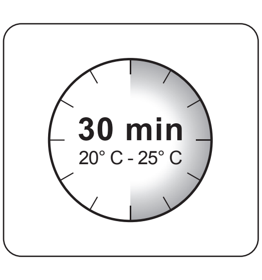






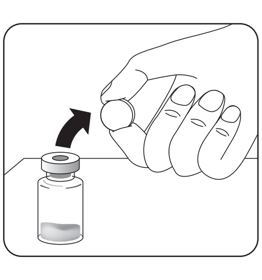
Step 1 – Assemble components

Take out dose pack



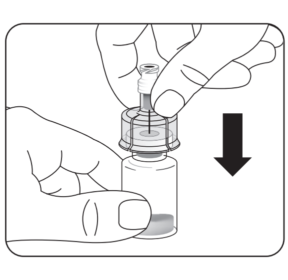
Wait 30 minutes
Remove 1 dose pack from the refrigerator and allow to sit at room temperature for at least **30 minutes** before reconstituting.
Do not warm any other way.

Connect vial adapter to vial

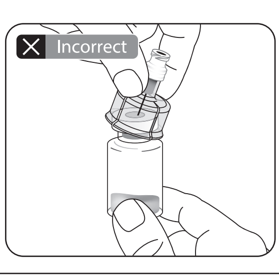


Remove cap from vial
Flip off colored cap from vial.
Wipe top of the gray stopper with an alcohol swab.
Allow to air dry.
Do not remove gray rubber stopper.

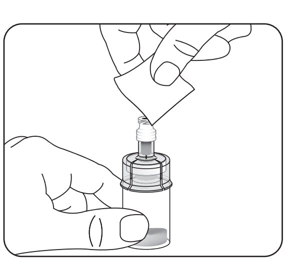
Prepare vial adapter
Peel back the blister pouch and remove the vial adapter by holding between the white luer cap and the skirt.
Do not touch spike tip or luer connection point at any time. This will result in contamination.



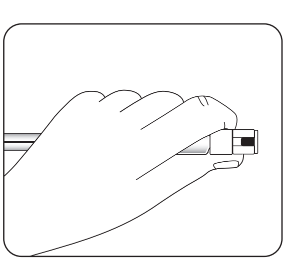
Connect vial adapter to vial
Place vial on a hard surface and hold by the base. Center vial adapter over the gray rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place, confirmed by an audible "click".
Do not place vial adapter on at an angle or solvent may leak upon transfer to the vial.



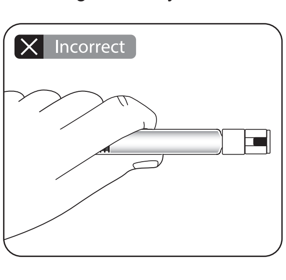
Connect prefilled syringe to vial adapter

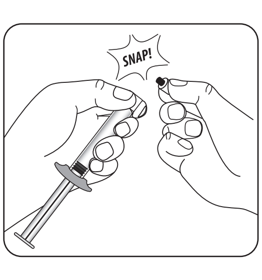


Swab connection point
Keep vial vertical to prevent leakage.
Hold base of vial and swab the luer connection point (blue circle) of the vial adapter with an alcohol wipe and allow to dry prior to attaching the syringe.
Do not shake.
Do not touch luer connection point on vial adapter. This will result in contamination.

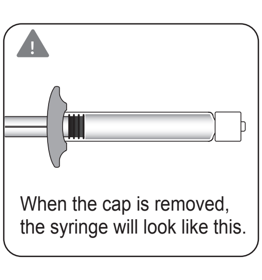


Use proper grip
Hold by white collar at the tip of the syringe.
Do not hold syringe by the glass barrel during assembly.

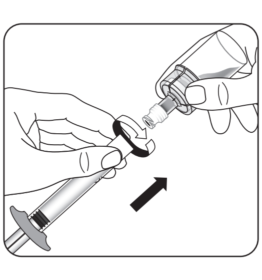




Remove cap
Holding the white collar, snap off the white cap.
Do not twist or cut off the white cap.
Do not touch syringe tip. This will result in contamination.

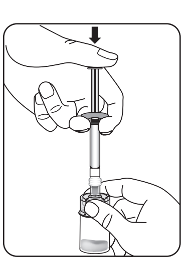

When the cap is removed, the syringe will look like this.

The broken-off cap can be discarded.



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.

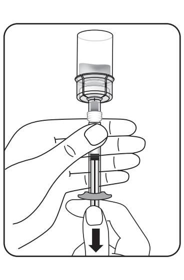
Step 2 – Reconstitute microspheres



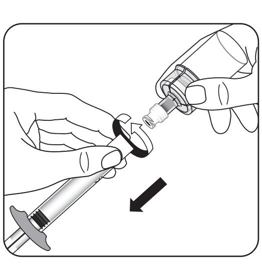
Inject solvent
Inject entire amount of solvent from syringe into the vial.

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.

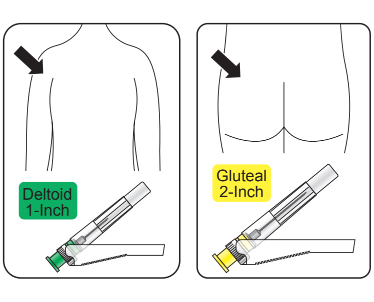


Transfer suspension to syringe
Invert vial completely. Slowly pull plunger rod down to withdraw entire content from the vial into the syringe.

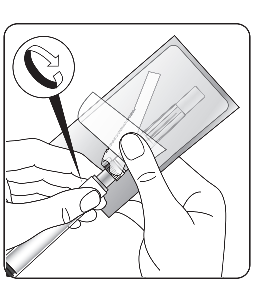


Remove vial adapter
Hold white collar on the syringe and unscrew from vial adapter.
Discard both vial and vial adapter appropriately.

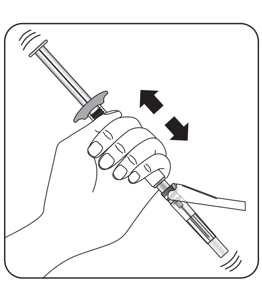
Step 3 – Attach needle



Select appropriate needle
Choose needle based on injection location (gluteal or deltoid).

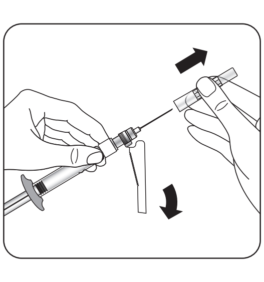


Attach needle
Peel blister pouch open part way and use to grasp the base of the needle, as shown.
Holding the white collar on the syringe, attach syringe to needle luer connection with a firm **clockwise twisting motion** until snug.
Do not touch needle luer opening. This will result in contamination.

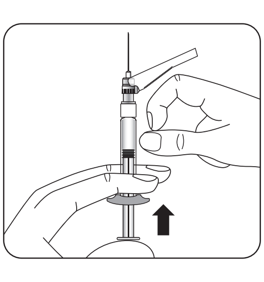


Resuspend microspheres
Fully remove the blister pouch.
Just before injection, shake syringe vigorously again, as some settling will have occurred.

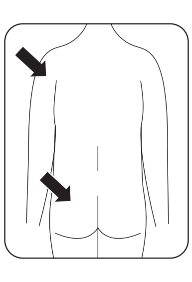
Step 4 – Inject dose



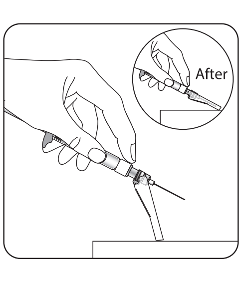
Remove transparent needle protector
Move the needle safety device back towards the syringe, as shown. Then hold white collar on syringe and carefully pull the transparent needle protector straight off.
Do not twist transparent needle protector, as the luer connection may loosen.



Remove air bubbles
Hold syringe 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.



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.

teva