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

The medicine is dispensed with a doctor's prescription only

Risperdal Consta® 25 mg

Risperdal Consta® 37.5 mg

Risperdal Consta® 50 mg

Powder for preparation of suspension for injection

Active ingredient

Risperdal Consta 25 mg contains:
Risperidone 25 mg/vial
Risperdal Consta 37.5 mg contains:
Risperidone 37.5 mg/vial
Risperdal Consta 50 mg contains:
Risperidone 50 mg/vial

Inactive ingredients and allergens in the preparation – see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. 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 with psychosis-related dementia.
Elderly patients with psychosis-related dementia treated with antipsychotic medicines are at an increased risk of death. Risperdal Consta is not approved for the treatment of patients with psychosis-related dementia.

1. WHAT IS THE MEDICINE INTENDED FOR?

Risperdal Consta is indicated for the treatment of schizophrenia and schizoaffective disorders.
Risperdal Consta is indicated as monotherapy for the maintenance treatment of bipolar disorder to delay occurrence of mood episodes.
Risperdal Consta is indicated for adjunctive maintenance treatment to delay occurrence of mood episodes in patients with frequently relapsing bipolar disorder.

Therapeutic group: atypical antipsychotics.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:

You are sensitive (allergic) to the active ingredient (risperidone) or its metabolite (paliperidone) or to any of the additional ingredients contained in the medicine (see section 6 “Further Information”). Hypersensitivity reactions, including anaphylactic reaction and angioedema, have been reported in patients treated with risperidone and paliperidone.

Special warnings regarding use of the medicine

- Studies in elderly patients with dementia have shown that taking Risperdal alone or with furosemide is associated with a higher frequency of deaths. Tell the doctor if you are taking furosemide, a medicine for treating high blood pressure, for certain heart problems or for edemas in the body due to build-up of fluids.
- Risperdal Consta is not approved for use in elderly patients with dementia. In elderly patients suffering from dementia, sudden change in mental state or sudden weakness or numbness of the face, arms or legs, especially on one side of the body, or instances of slurred speech have been seen. If any of these occur, even for a short period of time, seek medical attention immediately.
- A state of confusion, reduced consciousness, high fever or muscle stiffness may occur when using the medicine (a condition called Neuroleptic malignant syndrome). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. If this effect occurs, refer to a doctor immediately and inform him that you are taking Risperdal Consta.
- Prolonged treatment with Risperdal Consta may cause irreversible, involuntary twitching of the face (Tardive dyskinesia). If this effect occurs, refer to the doctor. This effect may also occur after discontinuation of treatment.
- Risperdal 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 preexisting diabetes have been observed in patients taking Risperdal. The doctor must monitor signs of hyperglycemia. The doctor must monitor sugar levels regularly **in every patient** receiving Risperdal Consta.
- Refer to the doctor if you are suffering from excessive thirst or urination.
- Risperdal may lead to increased levels of the prolactin hormone. This may cause side effects, such as menstrual cycle problems, fertility problems in women and breast swelling in men.
- During cataract (an eye disease manifested by cloudiness of the eye lens) surgery, the pupil (the black circle in the middle of the eye) may not increase in size as needed. Also, the iris (the colored part of the eye) may become floppy during surgery, which may lead to eye damage. If you are planning to have an operation on your eye, tell your doctor that you are taking this medicine.
- If you have never taken Risperdal in any other dosage form, start with Risperdal that is taken orally before starting treatment with Risperdal Consta. Even if you have previously been treated with oral Risperdal, rarely, an allergic reaction

occurs after receiving a Risperdal Consta injection. Seek medical attention immediately if you experience a rash, swelling of the throat, itching or breathing problems, since these may be signs of a serious allergic reaction.

Before treatment with Risperdal Consta, tell the doctor if:

- You are suffering, or have suffered in the past, from impaired function of the heart, especially heart rhythm disorders, abnormal electrical activity of the heart or if you are taking medicines that change the electrical activity of the heart – use Risperdal Consta with caution and only after consulting the doctor.
- You tend to have low blood pressure, are taking medicines to treat high blood pressure, since low blood pressure may result from concomitant use of Risperdal Consta and antihypertensives.
- You or someone in your family has or has had blood clots. Blood clots in the lungs and legs have been observed in patients taking Risperdal Consta. Blood clots in the lungs may be fatal.
- You suffered in the past from low white blood cell counts (even if resulting from use of other medicines), since, in rare cases, very low white blood cell (required to protect against infections) level was observed in patients who took Risperdal Consta. The doctor may perform blood tests to check white blood cell counts.
- You suffer from a heart or vascular disease, diabetes, Parkinson's, dementia associated with Lewy bodies or from epilepsy. You may need medical supervision while being treated with Risperdal Consta and your dose or treatment may have to be adjusted.
- You have risk factors for stroke, such as high blood pressure, cardiovascular problems or problems of blood flow to the brain.
- You are a man and have ever suffered from prolonged or painful erection.
- You suffer from problems controlling body temperature or 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 tumor.
- You have ever suffered from involuntary movements of the tongue, mouth or face.
- You are at risk of aspiration pneumonia.

Children and adolescents

Risperdal Consta 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 pharmacist. In particular, if you are taking:

- Medicines that reduce the ability to react (sedatives, narcotic painkillers, certain antihistamines – certain medicines to treat allergy, certain antidepressants). Risperdal Consta may increase their effect.

- Medicines used to treat Parkinson's disease, such as dopamine agonists (e.g., levodopa).
- Medicines for treatment of high blood pressure; taking these medicines together with Risperdal Consta may cause the blood pressure to drop too low.
- Medicines that may change the electrical activity of the heart, such as (but not restricted to) medicines for treatment of malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, diuretics or other medicines affecting the levels of body salts (sodium, potassium, magnesium).
- Clozapine.
- Phenytoin, rifampicin and phenobarbital.
- Carbamazepine, a medicine mainly used treat epilepsy or severe pain attacks in the face (Trigeminal neuralgia). This medicine may decrease the level of Risperdal Consta in the blood.
- Furosemide (see section – "Special warnings regarding use of the medicine").
- Methylphenidate, medicines to treat attention deficit disorder (ADHD). Extrapyramidal symptoms (dystonia and dyskinesia) have been reported in patients taking methylphenidate and Risperdal Consta, when there was a change in the dosage of one of these medicines.
- Quinidine (a medicine for the treatment of a certain type of heart problems).
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants.
- Beta-blockers (used to treat high blood pressure).
- Phenothiazines (such as medicines used to treat psychosis or as sedatives).
- Cimetidine, ranitidine (medicines that lower the acidity of stomach).
- Itraconazole and ketoconazole (for treating fungal infections).
- Certain medicines for the treatment of HIV/AIDS, such as ritonavir.
- Verapamil, to treat high blood pressure and/or abnormal heart rhythm.
- Sertraline and fluvoxamine, to treat 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 consumption of alcohol

Do not drink wine or alcoholic beverages during the course of treatment with the medicine. The medicine may increase the effect of the alcohol.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant or are planning to become pregnant, consult the doctor, who will decide if you can use Risperdal Consta.

For your information, the use of Risperdal Consta 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 treated with the medicine must check if their child develops tremors, muscle stiffness and/or weakness, sleepiness, restlessness, respiratory stress or

difficulty feeding. If the baby is suffering from these effects, refer for medical assistance.

Fertility

Risperdal Consta may cause an increase in levels of the prolactin hormone, which may affect fertility (see section 4 “Side Effects”).

If there is an effect on fertility, this effect is reversible.

Driving and use of machinery

The medicine may affect alertness or the ability to drive. Do not drive or operate dangerous machinery when using the medicine before the doctor assesses the affect the medicine has on you.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Risperdal Consta is given as an intramuscular injection in the buttock or into the deltoid 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 usual dosage is generally 25 mg every two weeks as an intramuscular injection. A higher dose (37.5 mg or 50 mg) may be necessary.

The doctor may instruct you to take Risperdal tablets for the first three weeks following the first injection.

Do not exceed the recommended dose.

If you accidentally take a higher dosage

Overdose is less likely with Risperdal Consta injections than with orally taken Risperdal (e.g., tablets, solution).

One or more of the following signs may occur in cases of overdose: reduced consciousness, drowsiness, sleepiness, excessive trembling, muscle stiffness, increased heart rate and low blood pressure. There have been reports of abnormal electrical conduction in the heart (prolongation of the QT interval) and convulsions. Cases of overdose can also occur if you are taking other medicines together with Risperdal.

If you experience one of the listed symptoms or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take this medicine at the designated time, consult the doctor or nurse at the clinic where you are being treated.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop the treatment with the medicine without consulting the doctor, and then only in a controlled manner.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Risperdal Consta may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor immediately if:

- You experience a blood clot in the veins, especially in the legs (symptoms include swelling, pain and redness in the leg), which can travel through blood vessels to the lungs, and cause chest pain and difficulty breathing. If you notice any of these symptoms, seek medical advice immediately.
- You have dementia and experience a sudden change in your mental state or sudden weakness or numbness of the face, arms or legs, especially on one side of the body, or slurred speech, even for a short period of time. These may be symptoms of a stroke. If any of them occur, refer for medical attention immediately.
- You experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called Neuroleptic malignant syndrome). You may need immediate medical treatment.
- You are a man and experience prolonged or painful erection. This effect is called priapism. You may need immediate medical treatment.
- You experience involuntary rhythmic movements of the tongue, mouth or face. There may be a need to discontinue use of the medicine.
- You experience a severe allergic reaction characterized by fever, swelling of the mouth, face, lips or tongue, shortness of breath, itching, skin rash or drop in blood pressure. Even if you have previously taken oral risperidone and did not suffer from an allergic reaction, in rare cases an allergic reaction may occur after receiving an injection of Risperdal Consta.

Additional side effects

Very common side effects (effects that occur in more than one in ten users):

- Symptoms of the common cold
- Difficulty falling asleep or difficulty staying asleep
- Depression, anxiety
- Parkinsonism, manifested by impaired or slow movement, sensation of muscle stiffness or tightness of muscles and sometimes even a sensation of movement freezing up 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 in 100 users):

- Pneumonia, bronchitis, sinus infection, urinary tract infection, flu-like illness
- Anemia
- Risperdal Consta may increase levels of the hormone prolactin, as can be seen in blood tests (that can, but not necessarily, cause symptoms). Symptoms of high prolactin levels include: among men – breast swelling, difficulty in getting or maintaining erection or any other problem relating to sexual function. Among women – breast discomfort, breast milk discharge, absence of menstruation or other menstrual cycle disorders
- High blood sugar levels, weight gain, weight loss, decreased or increased appetite
- Sleeping problems, irritability, decreased sexual drive, restlessness, feeling sleepy or less alert
- Dystonia – an effect which involves slow or prolonged and involuntary muscle contraction. 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 that can include repetitive, spastic or writhing movements
- Tremor
- Blurred vision
- Rapid heart rate
- Low blood pressure, high blood pressure
- Shortness of breath, sore throat, cough and stuffy nose
- Abdominal pain or discomfort, vomiting, gastrointestinal infection, constipation, diarrhea, indigestion, dry mouth and toothaches
- Rash
- Muscle spasms, muscle or bone pain, back pain, joint pain
- Urinary incontinence (inability to hold in)
- Erection problems
- Absence of menstruation
- Breast milk leakage
- Swelling of the body, hands or legs, fever, chest discomfort, weakness, fatigue
- Pain
- Injection site reaction including itching, pain or swelling
- Increased liver enzyme levels in the blood
- Falls

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Respiratory tract infection, bladder infection, ear infection, eye infection, tonsillitis, fungal infection of the nails, skin infection, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation resulting from exposure to mites, subcutaneous abscess

- Reduced white blood cell count, reduced platelet levels (blood cells that aid in stopping bleeding), reduced red blood cell count
- Allergic reaction
- Presence of sugar in the urine, diabetes or worsening of diabetes
- Loss of appetite that may result in malnutrition and weight loss
- Increased triglyceride and/or cholesterol (lipids) levels in the blood
- Elated mood (mania), confusion, difficulty reaching orgasm, nightmares
- Tardive dyskinesia – involuntary movements and/or spasms of the face, tongue or other parts of the body. If you experience involuntary and rhythmic movements of the tongue, mouth and face, refer to the doctor immediately. The doctor may tell you to stop treatment with Risperdal Consta
- Sudden cessation of blood flow to the brain (stroke or mini-stroke)
- Loss of consciousness, convulsions, fainting
- Incontrollable urge to move certain parts of the body, balance disorders, impaired coordination, dizziness when changing to a standing position, attention disturbances, speech problems, loss or problems with sense of taste, reduced skin sensitivity to pain and touch, tingling or numb sensation of the skin
- Eye infection, conjunctivitis, dry eyes, increased tears, redness of the eyes
- Spinning sensation (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (irregular heart rhythm), an interruption in conduction between the upper and lower parts of the heart, impaired electrical conduction of the heart, prolongation of the QT interval of the heart, slow heart rate, abnormal cardiac electrical tracing test results (electrocardiogram/ECG), awareness of abnormal heartbeats (palpitations)
- Low blood pressure upon standing up (as a result, some people taking Risperdal Consta may feel weak, dizzy, or may faint when suddenly moving to a standing or sitting position)
- Rapid and shallow breathing, congested respiratory tract, wheezing, nosebleed
- Stool incontinence (inability to hold in), difficulty swallowing, increased flatulence
- Itchiness, hair loss (alopecia), eczema, dry skin, skin redness, skin discoloration, acne, dandruff
- Increased blood CPK (creatine phosphokinase) levels, an enzyme released as a result of muscle injury or damage
- Joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine
- Ejaculation disorders
- Delayed menstruation, absence of menstruation or any other disorder relating to the menstrual cycle
- Breast development in men, sexual dysfunction, breast discomfort, vaginal discharge
- Swelling of the face, mouth, eyes or lips
- Chills, increased body temperature
- A change in the way you walk

- Thirst sensation, overall unwell feeling, feeling down
- Skin hardening
- Increased liver enzyme levels in the blood
- Procedural pain

Rare side effects (effects that occur in 1-10 in 10,000 users):

- 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, loss of or reduced consciousness, high fever and severe muscle stiffness
- Low level of consciousness/awareness
- Head shaking
- Disturbance with the movement of the eyes, eye rolling, oversensitivity of the eyes to light
- Abnormal heartbeat
- Blood clots in the legs, blood clots in the lungs
- Breathing difficulties (inability to breathe) when sleeping
- Pneumonia due to aspiration of food, lung congestion
- Crackly sounds from the lungs, voice problems, respiratory tract problems
- Pancreatitis, intestinal obstruction
- Skin rash related to taking a medicine, urticaria (allergic skin reaction), skin thickening, skin problems, skin bruising
- Muscle fiber breakdown and muscle pain
- Posture problems
- Enlargement of the breasts, discharge from the breasts
- Decreased body temperature, feeling of discomfort
- Yellowing of the skin and eyes (jaundice)

Very rare side effects (effects that occur in less than one in 10,000 users):

- Life-threatening complications as a result of uncontrolled diabetes
- Severe allergic reaction with swelling that may involve the throat and lead to difficulty breathing
- In very rare cases, an allergic reaction may occur after receiving an injection of Risperdal Consta, even in patients treated with orally administered Risperdal without having an allergic reaction. **Seek medical attention immediately if you suffer from a rash, swelling of the throat, itching or breathing difficulties, as these may be signs of a serious allergic reaction.**
- Lack of bowel muscle movement that causes blockage
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you have taken Risperdal Consta during the last three months. If you need to have cataract surgery, tell your

doctor if you are taking, or have taken, Risperdal Consta during the last three months.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- Dangerous reduction in the number of white blood cells of the type needed to protect against infections
- Severe allergic reaction characterized by fever, swollen mouth, face, lips or tongue, shortness of breath, itching, skin rash and sometimes a drop in blood pressure
- Extremely excessive intake of water that puts the body in danger
- Increased blood insulin levels (a hormone that regulates body sugar levels)
- Problem with blood vessels in the brain
- Unresponsive to stimuli
- Coma due to uncontrolled diabetes
- Sudden loss of vision or blindness
- Glaucoma (increased intraocular pressure), eyelid margin crusting
- Increased heartbeats upon standing up
- Flushing, swelling of the tongue
- Very hard stool
- Chapped lips
- Prolonged erection that may require surgical intervention
- Swelling of the breast glands
- Cold feeling in the hands and legs
- Symptoms of drug withdrawal
- Inflammation of the bowel
- Diabetes
- Worsening of preexisting diabetes
- Somnambulism
- Stevens-Johnson syndrome
- Toxic epidermal necrolysis (TEN)
- Ketoacidosis in patients with impaired glucose metabolism
- Catatonia
- Thrombotic thrombocytopenic purpura
- Serious injection site reactions including abscess, cellulitis, cyst, hematoma, necrosis, nodule, and ulcer
- Anaphylactic reaction
- Extrapyramidal symptoms (dystonia and dyskinesia) have been reported in patients taking methylphenidate and Risperdal Consta, 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 are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Storage conditions: Store refrigerated: 2°C-8°C.
Do not freeze.
Store in the original package and protect from light.
For immediate use after reconstitution.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Vial:
Polymer: 7525 DL JN1 (poly-d,1-lactide-co-glycolide)
Reconstitution liquid:
Carmellose sodium 40 mPa.s, sodium chloride, disodium hydrogen phosphate dihydrate, citric acid anhydrous, polysorbate 20, sodium hydroxide, water for injection.

What the medicine looks like and the contents of the package
The kit contains:
- A vial with risperidone powder, for preparation of a suspension for injection
- Pre-filled syringe that contains 2 ml reconstitution liquid
- Reconstitution adapter without a needle
- A needle for injection into the buttocks
- A needle for injection into the deltoid

The risperidone vial is made from clear glass with a grey rubber stopper, which has a colored plastic cap over it, and contains a white/off-white powder.
The pre-filled syringe contains a clear, transparent solution without visible particles.
The preparation is a prolonged-release formulation and is available in three dosages: Risperdal Consta 25 mg, Risperdal Consta 37.5 mg and Risperdal Consta 50 mg.

Manufacturer: Cilag AG, Hochstrasse 201 8200 Schaffnausen, Switzerland.

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Risperdal Consta 25 mg: 127-28-30619-11

Risperdal Consta 37.5 mg: 127-29-30620-12
Risperdal Consta 50 mg: 127-30-30621-12

Revised in February 2023 according to MOH guidelines.

RISP POWD PL SH 160323

מידע לצוות הרפואי

RISPERDAL CONSTA® 25 mg, 37.5 mg and 50 mg
Powder for Prolonged-Release Suspension
for Intramuscular Injection

1. INSTRUCTIONS FOR USE

For deltoid or gluteal intramuscular injection only

Important Information

RISPERDAL CONSTA® 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 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.

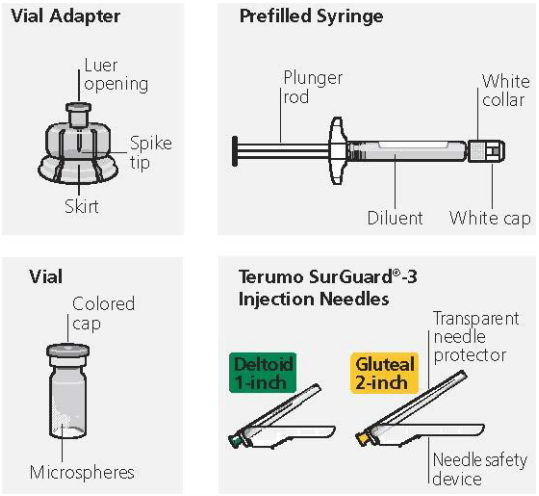
Proper dosing

The entire contents of the vial must be administered to ensure intended dose of RISPERDAL CONSTA® is delivered.

SINGLE-USE DEVICE

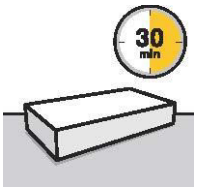
Do not reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

Dose pack contents



Step 1 Assemble components

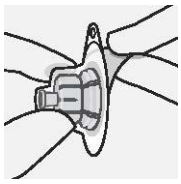
Take out dose pack



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.

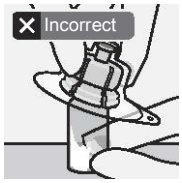
Remove cap from vial
Flip off colored cap from vial.
Wipe top of the grey stopper with an alcohol swab. Allow to air dry.
Do not remove grey rubber stopper.

Connect vial adapter to vial

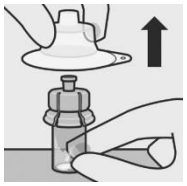


Prepare vial adapter
Hold sterile blister as shown. Peel back and remove paper backing.
Do not remove vial adapter from blister.
Do not touch spike tip at any time. This will result in contamination.

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.

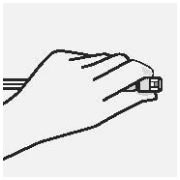


Connect prefilled syringe to vial adapter

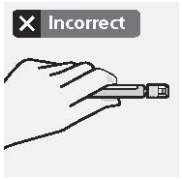


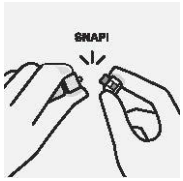
Remove sterile blister

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.

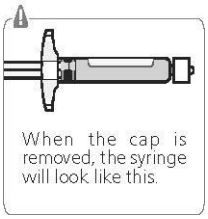


Use proper grip
Hold by white collar at the tip of the syringe.
Do not hold syringe by the glass barrel during assembly.

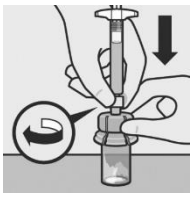




Remove cap
Holding the white collar, snap off the white cap.
Do not twist or cut off the white cap.
Do not touch syringe tip. This will result in contamination.

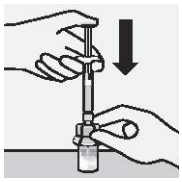


The broken-off cap can be discarded.



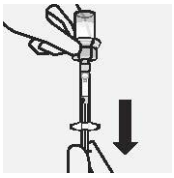
Connect syringe to vial adapter
Hold vial adapter by skirt to keep stationary.
Hold syringe by white collar then insert tip into the luer opening of the vial adapter.
Do not hold the glass syringe barrel. This may cause the white collar to loosen or detach.
Attach the syringe to the vial adapter with 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

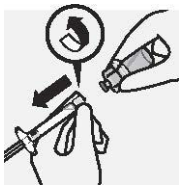


Inject diluent
Inject entire amount of diluent from syringe into the vial.

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.



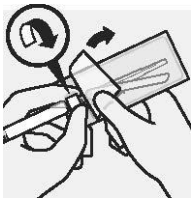
Transfer suspension to syringe
Invert vial completely. Slowly pull plunger rod down to withdraw entire contents from the vial into the syringe.



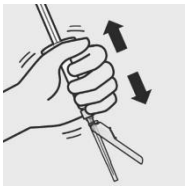
Remove vial adapter
Hold white collar on the syringe and unscrew from vial adapter.
Tear section of the vial label at the perforation. Apply detached label to the syringe for identification purposes.
Discard both vial and vial adapter appropriately.

Step 3	Attach needle

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

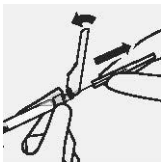


Attach needle
Peel blister pouch open part way and use to grasp the base of the needle, as shown.
Holding the white collar on the syringe, attach syringe to needle luer connection with a firm **clockwise twisting motion** until snug.
Do not touch needle luer opening. This will result in contamination.

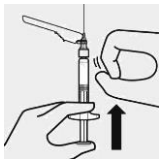


Resuspend microspheres
Fully remove the blister pouch.
Just before injection, shake syringe vigorously again, as some settling will have occurred.

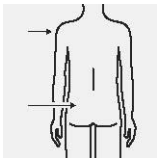
Step 4 **Inject dose**



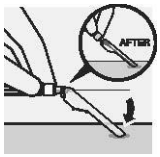
Remove transparent needle protector
Move the needle safety device back towards the syringe, as shown. Then hold white collar on syringe and carefully pull the transparent needle protector straight off.
Do not twist transparent needle protector, as the luer connection may loosen.



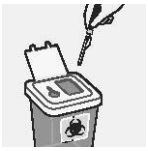
Remove air bubbles
Hold needle upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.



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.



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

RISPERDAL CONSTA® is available in dosage strengths of 25 mg, 37.5 mg, and 50 mg risperidone. It is provided as a single-use dose pack, consisting of a vial containing the risperidone microspheres, a prefilled syringe containing 2 mL of diluent for RISPERDAL CONSTA®, a vial adapter, and two Terumo SurGuard® 3 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

RISPERDAL CONSTA® (risperidone) is available in dosage strengths of 25 mg, 37.5 mg, or 50 mg risperidone. It is provided as a single-use dose pack, consisting of a vial containing the risperidone microspheres, a prefilled syringe containing 2 mL of diluent for RISPERDAL CONSTA®, a vial adapter, and two Terumo SurGuard® 3 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).

25-mg vial/kit 78 mg (equivalent to 25 mg of risperidone) of a white to off-white powder provided in a vial with a flip-off cap.

37.5-mg vial/kit 116 mg (equivalent to 37.5 mg of risperidone) of a white to off-white powder provided in a vial with a flip-off cap.

50-mg vial/kit 152 mg (equivalent to 50 mg of risperidone) of a white to off-white powder provided in a vial with a flip-off cap.

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 2 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 and Handling

The entire dose pack should be stored in the refrigerator (2°-8°C) and protected from light.

Keep out of the sight and reach of children.

Manufacturer: Cilag AG, Hochstrasse 201 8200 Schaffnausen, Switzerland.

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Marketing Authorization Numbers

Risperdal Consta 25 mg: 127-28-30619-11

Risperdal Consta 37.5 mg: 127-29-30620-12

Risperdal Consta 50 mg: 127-30-30621-12

Revised in February 2023 according to MOH guidelines.