## Risperidone Teva 37.5 mg Risperidone Teva 50 mg

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

Risperidone Teva 25 mg contains: 25 mg risperidone in a vial Risperidone Teva 37.5 mg contains: 37.5 mg risperidone in a vial Risperidone Teva 50 mg contains: 50 mg risperidone in a vial For information about inactive ingredients see

Active ingredient:

section 6 - "Additional information" 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? schizophrenia and schizoaffective disorders

# Risperidone Teva in intended for the treatment of

the occurrence of mood episodes.

Risperidone Teva is intended as a maintenance monotherapy for bipolar disorder, in order to delay

## 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. <u>BEFORE USING THE MEDICINE</u> 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).

### 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 these effects occur, 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.

doctor must monitor the appearance of signs

of hyperglycemia. The doctor must monitor

sugar levels regularly in each patient receiving

Refer to the doctor if you suffer from increased

Risperidone may cause an increase in the levels

of the hormone prolactin. This may cause side

effects such as menstrual cycle problems, fertility

problems in women and swelling of the breasts in

the eye) may not expand 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

Risperidone Teva

thirst or increased urination.

- men. 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
- 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

Before treatment with Risperidone Teva, inform

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

acute allergic reaction.

the doctor if:

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

Teva, and the dosage or treatment may need to

You have risk factors for stroke, such as high

blood pressure, heart and vascular problems or

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

be adjusted.

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

You have ever suffered from involuntary

problems with blood flow in the brain.

prolactin-dependent cancerous tumor.

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

diuretic preparations or other medicines that affect

the levels of salts in the body (sodium, potassium,

may reduce the level of Risperidone Teva in the

- 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,
- 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
- Furosemide (see section "Special warnings regarding the use of the medicine"). Methylphenidate, a medicine for treatment of attention deficit hyperactivity disorder (ADHD). symptoms Extrapyramidal (dystonia dyskinesia) have been reported in patients taking

methylphenidate and risperidone, when there was

a change in the dosage of one of these medicines.

Phenothiazines (such as medicines for treatment

- Quinidine (a medicine for treatment of certain heart problems). Antidepressants, such as paroxetine, fluoxetine, tricyclic antidepressants. Beta blockers (for treatment of high blood pressure)

25 mg, 37.5 mg and 50 mg

Powder and solvent for preparation of a

prolonged-release suspension for intramuscular

Risperidone Teva requires close attention to these step-by-step instructions for use to help ensure

Prefilled Syringe

Plunger rod

of psychosis or for sedation).

Risperidone Teva

successful administration.

Vial Adapter

Step 1

SINGLE-USE DEVICE Dose pack contents:

Skirl

Take out dose pack

Wait 30 minutes

before reconstituting.

Luer connection

Luer cap

Spike tip

30 min 20° C - 25° C

Remove 1 dose pack from the

refrigerator and allow to sit at room

temperature for at least 30 minutes

injection

1. INSTRUCTIONS FOR USE For deltoid or gluteal intramuscular injection Important information

fungal infections). Certain medicines for treatment of AIDS, such as ritonavir (HIV). Verapamil (for treatment of high blood pressure

need a different dosage of risperidone.

Pregnancy, breastfeeding and fertility

Use of the medicine and alcohol consumption

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

If you are breastfeeding, consult the doctor before

drive. Do not drive or operate dangerous machinery

while using the medicine before the doctor assesses

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

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

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

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

Do not exceed the recommended dose.

If you accidentally took a higher dosage:

the effect of the medicine on you.

be determined only by the doctor.

body. Do not inject intravenously.

the first injection.

3. HOW SHOULD YOU USE THE

Sertraline and fluvoxamine (for treatment of

depression and other psychiatric disorders). If

and/or abnormal heart rate).

enhance the effect of alcohol.

symptoms in the newborn.

Pregnancy

Breastfeeding

- Peel back the blister pouch and Flip off colored cap from vial. remove the vial adapter by holding Wipe top of the gray stopper with an between the white luer cap and the
- Use proper grip

Holding the white collar, snap off the Hold by white collar at the tip of the white cap. Do not hold syringe by the glass 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.

**Reconstitute microspheres** 

Remove cap

Transfer suspension to syringe

content from the vial into the syringe.

- weakness, neck pain while urinating Ejaculation disorders
- muscle injury or damage
- Frequent passing of urine, inability to urinate, pain

- 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):
- responsible for protecting against infections
- Neuroleptic malignant syndrome: confusion, reduced or lack of consciousness, high fever and severe muscle stiffness Low level of consciousness/awareness
- (allergic skin reaction), thickening of the skin, skin problems, skin bruises Breakdown of muscle fibers and muscle pain Posture problems
- 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

Enlarged breasts, discharge from the breasts

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.

endangers the body

margin crusting

Very hard stool

disturbance

Reporting side effects

position

- 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,
- 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

Increased insulin levels in the blood (a hormone

that regulates sugar levels in the body)

Flushing, swelling of the tongue

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

Increased heartbeats when switching to a standing

- Cracked lips Prolonged erection that may require surgical intervention Swelling of glands in the chest
- Diabetes, worsening of pre-existing diabetes Sleepwalking Stevens-Johnson syndrome Toxic epidermal necrolysis (TEN)
- lumps and ulcer Anaphylactic reaction Extrapyramidal symptoms (dystonia dyskinesia) have been reported in patients taking methylphenidate and risperidone, when there was

Thrombotic thrombocytopenic purpura

- 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?
- Storage conditions: store refrigerated (2°C-8°C) and protect from light. 6. ADDITIONAL INFORMATION: In addition to the active ingredient the medicine also contains: In the vial: poly(D,L-lactide-co-glycolide) In the reconstitution solvent: Carmellose sodium, sodium chloride, disodium
- What does the medicine look like and what are the contents of the package? The kit contains: A vial with risperidone powder Syringe that contains 2 ml reconstitution solvent Reconstitution adapter

polysorbate 20, sodium hydroxide, water for injection.

hydrogen phosphate dihydrate, citric acid

transparent solution. 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:

The leaflet was revised in June 2023 in accordance

Risperidone Teva 25 mg: 173-17-36592-99

Risperidone Teva 50 mg: 173-19-36594-99

with the Ministry of Health guidelines.

Risperidone Teva 37.5 mg: 173-18-36593-99

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 MW0623

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

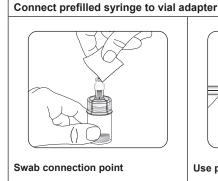
use only. Any attempt to re-process the device for

subsequent re-use may adversely affect the integrity

of the device or lead to deterioration in performance.

#### alcohol swab. Do not warm any other way. Allow to air dry. Do not touch spike tip or luer connection point at any time. This will Do not remove gray rubber stopper. result in contamination.

Prepare vial adapter



## connection point (blue circle) of the vial adapter with an alcohol wipe and allow to dry prior to attaching the syringe. Do not shake.

contamination.

Keep vial vertical to prevent leakage.

Hold base of vial and swab the luer

Do not touch luer connection point on vial adapter. This will result in

Step 2

Inject solvent

syringe into the vial.

under pressure.

Step 3

Inject entire amount of solvent from

Vial contents will now be

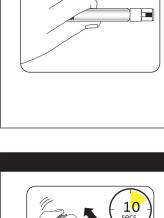
rod down with thumb.

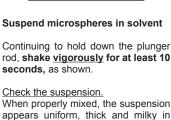
Keep holding the plunger



syringe.

barrel during assembly.





color. Microspheres will be visible in

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

Attach needle

contamination.

Attach needle

Inject

Immediately inject entire contents of syringe intramuscularly (IM) into the gluteal or deltoid muscle of the patient. Gluteal injection should be





Just before injection, shake syringe vigorously

again, as some settling will have occurred.

needle provided in the dose pack.

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

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

Inject dose

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

> device made into the upper-outer quadrant of the gluteal area. Avoid needle stick injury: Do not use two hands.

Do not intentionally disengage or mishandle the needle safety

Keep out of the sight and reach of children.

stiffness, increased heart rate and low blood pressure. There have been reports of cases of abnormal Breathing difficulties (inability to breathe) while 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 If you experience any of the symptoms described or Risperidone Teva is not approved for use in elderly if a child accidentally took the medicine, refer to the people with dementia. In elderly patients suffering doctor or to a hospital emergency room immediately from dementia, cases of sudden change in the

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

Do not take medicines in the dark! Check the label

and the dose every time you take the medicine.

If you have any other questions regarding the use of

Wear glasses if you need them.

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 have fever, muscle stiffness, sweating or a decrease in the level of consciousness (a disorder

called: neuroleptic malignant syndrome). You may

You are a man and you experience prolonged

or painful erection. This phenomenon is called

priapism. You may need immediate medical

You have involuntary rhythmic movements of

the tongue, mouth or face. You may need to

You have 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.

Very common side effects (effects that occur in

require immediate medical treatment.

discontinue the use of the medicine.

Additional side effects

Headache

users out of 100):

prolactin levels include:

decrease or increase in appetite

eyes, mouth, tongue or jaw

toothache

joint pain

swelling

Erectile dysfunction

Lack of menstrual period

worsening of diabetes

and weight loss

(lipids) in the blood

orgasm, nightmares

Tardive dyskinesia -

Administer dose as soon

reconstitution to avoid settling

White collar

Solvent

Assemble components Connect vial adapter to vial

Remove cap from vial

White

Leakage of milk from the breasts

discomfort, weakness, tiredness

Rash

Pneumonia,

dysfunction.

menstrual cycle.

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

Common side effects (effects that occur in 1-10

(bronchitis), sinus infection, urinary tract infection,

Risperidone may increase the levels of the

hormone prolactin, which can be seen in blood

tests (an effect which can, but not necessarily,

cause symptoms). The symptoms of high

In men - breast swelling, difficulty reaching or

maintaining an erection or any other sexual

In women - sensation of discomfort in the

breasts, discharge of milk from the breasts, lack

of menstrual period or other disorders of the

High blood sugar levels, weight gain, weight loss,

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

Dyskinesia - involuntary muscle movement which

inflammation of the bronchi

drooling and loss of facial expression

may include repetitive movements, twitching or writhing Tremor Rapid heartbeat Low blood pressure, high blood pressure Shortness of breath, sore throat, cough and nasal congestion

vomiting, infection of the gastrointestinal system,

constipation, diarrhea, indigestion, dry mouth and

Muscle cramps, muscle or bone pain, back pain,

Swelling in the body, hands or legs, fever, chest

Injection site reaction including itch, pain or

Increased levels of liver enzymes in the blood

Urinary incontinence (inability to hold in)

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 (tiny insect), 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

Loss of appetite which may lead to malnutrition

Increased levels of triglycerides and/or cholesterol

Elated mood (mania), confusion, difficulty reaching

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

involuntary movements

as possible after

Coloured cap

Microspheres

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

Vial

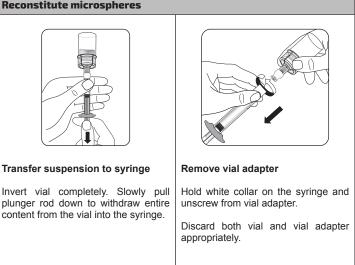
Terumo SurGuard®3 Transparent needle protector Injection Needles Needle

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. X In

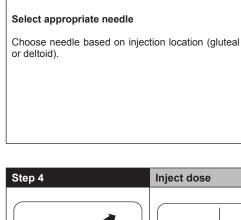
Connect vial adapter to vial

Place vial on a hard surface and

hold by the base. Center vial adapter



This may cause the white collar to



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.

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

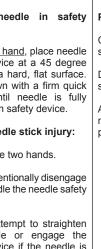
device for deltoid administration and a 20G TW

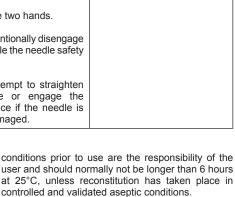
2-inch needle with needle protection device for

gluteal administration.

syringe to needle luer connection with a firm clockwise twisting motion until snug. Do not touch needle luer opening. This will result in

Secure





Do not administer intravenously. device. 3. HOW SUPPLIED/STORAGE AND 2. DOSAGE FORMS AND STRENGTHS **HANDLING** 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

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

teva

using the medicine. Breastfeeding mothers who change to a standing or sitting position) are being treated with the medicine need to check Rapid and shallow breathing, congestion in the whether their baby develops tremor, muscle stiffness respiratory tract, wheezing, nosebleed and/or weakness, sleepiness, irritability, respiratory Stool incontinence (inability to hold in), difficulty distress or difficulty feeding. If the baby suffers from swallowing, excessive gas in the gastrointestinal these effects, seek medical assistance. Itch, hair loss (alopecia), eczema, dry skin, redness Risperidone Teva may cause an increase in the in the skin, skin discoloration, acne, dandruff levels of the hormone prolactin, which may affect Increased CPK (creatine phosphokinase) levels fertility (see section 4 "Side effects"). If there is an in the blood, an enzyme released as a result of effect on fertility, this effect is reversible. Driving and operating machinery Joint stiffness, swelling of the joints, muscle The medicine may affect alertness or the ability to

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,

you start or stop taking these medicines, you may and touch, sensation of tingling or numbness of Eye infection, conjunctivitis, dryness in the eyes, Do not drink wine or other alcoholic beverages during excessive tearing, redness of the eyes treatment with the medicine, the medicine may Sensation of dizziness (vertigo), ringing in the Atrial fibrillation (irregular heart rate), an interruption

to the doctor immediately. The doctor may instruct

Sudden cessation of blood flow to the brain (stroke

dizziness when standing up, attention disorders,

speech problems, loss of or problems with the

sense of taste, reduced skin sensitivity to pain

in the conduction between the upper and lower

certain people taking Risperidone Teva may feel

weakness, dizziness, or may faint upon sudden

abnormal

coordination.

you to stop the treatment with Risperidone Teva

Loss of consciousness, convulsions, fainting Uncontrollable urge to move certain body parts,

disorders.

or mini-stroke)

balance

Reduced levels of white blood cells that are Abnormal secretion of the hormone that regulates urine volume Low blood sugar levels Excessive drinking of water Lack of emotion

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

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

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

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):

Sensation of coldness in the legs and hands Symptoms of medicine withdrawal Inflammation of the bowel

Ketoacidosis in patients with glucose metabolism

Severe reactions at the injection site including

abscess, cellulitis, cyst, hematoma, necrosis,

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

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

mentioned in this leaflet, consult your doctor.

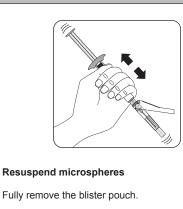
Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor. Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

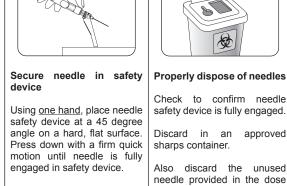
Green safety needle for injection into the shoulder Yellow safety needle for injection into the buttock muscle The risperidone vial is made of transparent glass with a rubber cap that has a colored plastic seal on top of it, and contains white/off-white powder. The syringe is made of glass and contains a clear

INFORMATION FOR THE HEALTHCARE PROVIDER

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.

loosen or detach.





Do not attempt to straighten the needle or engage the safety device if the needle is bent or damaged. controlled and validated aseptic conditions.