

12. Storage:

- Keep this medicine out of the sight and reach of children.
- Do not freeze
- Once the bottle is opened, any unused portion of Risperidone Sugar Free Oral Solution should be discarded after 2 months.

13. Other information

Active substance is Risperidone

The other ingredients are:

Benzoic acid, Tartaric acid, Hydrochloric acid

14. Packaging:

Amber glass bottle containing 120 ml of Risperidone with graduated measure (pipette) and a leaflet in box.

References:

- 1) Drug facts and comparisons-2010
- 2) Martindale 38
- 3) BNF-81
- 4) <https://www.medicines.org.uk>

liver enzyme called gamma-glutamyltransferase) in your blood, increased liver enzymes in your blood

Rare side effects (may affect up to 1 in 1,000 people):

- Infection
- Inappropriate secretion of a hormone that controls urine volume
- Sleep walking
- Sleep-related eating disorder.
- Sugar in the urine, low blood sugar, high blood triglycerides (a fat)
- Lack of emotion, inability to reach orgasm
- Not moving or responding while awake (catatonia)
- Blood vessel problems in the brain
- Shaking of the head
- Glaucoma, (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken Risperidone Sugar Free Oral Solution. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine.
- Dangerously excessive intake of water
- Irregular heart beat
- Trouble breathing during sleep (sleep apnea), fast, shallow breathing
- Inflammation of the pancreas, a blockage in the bowels
- Swollen tongue, chapped lips, rash on skin related to drug
- Dandruff
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)
- A delay in menstrual periods, enlargement of the glands in your breasts, breast enlargement, discharge from the breasts
- Increased insulin (a hormone that controls blood sugar levels) in your blood
- Hardening of the skin
- Decreased body temperature, coldness in arms and legs
- Symptoms of drug withdrawal

Very rare (may affect up to 1 in 10,000 people):

- Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing
- Lack of bowel muscle movement that causes blockage.

Additional side effects in children and adolescents:

In general, side effects in children are expected to be similar to those in adults. The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults: feeling sleepy or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor (shaking), diarrhea, and incontinence (lack of control) of urine.

- Increased cholesterol in your blood
- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares
- Unresponsive to stimuli, loss of consciousness, low level of consciousness
- Convulsion (fits), fainting
- A restless urge to move parts of your body, balance disorder, abnormal coordination, dizziness upon standing, disturbance in attention, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling, pricking, or numbness skin
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- Sensation of spinning (vertigo), ringing in the ears, ear pain
- Atrial fibrillation (an abnormal heart rhythm), an interruption in conduction between the upper and lower parts of the heart, abnormal electrical conduction of the heart, prolongation of the QT interval from your heart, slow heart rate, abnormal electrical tracing of the heart (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations)
- Low blood pressure, low blood pressure upon standing (consequently, some people taking Risperidone Sugar Free Oral Solution may feel faint, dizzy, or may pass out when they stand up or sit up suddenly), flushing
- Pneumonia caused by inhaling food, lung congestion, congestion of breathing passages, crackly lung sounds, wheezing, voice disorder, breathing passage disorder
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind
- Hives (or «nettle rash»), itching, hair loss, thickening of skin, eczema, dry skin, skin discoloration, acne, flaky, itchy scalp or skin, skin disorder, skin lesion
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain
- Frequent passing of urine, inability to pass urine, pain when passing urine
- Erectile dysfunction, ejaculation disorder
- Loss of menstrual periods, missed menstrual periods or other problems with your cycle (females),
- Development of breasts in men, leakage of milk from the breasts, sexual dysfunction, breast pain, breast discomfort, vaginal discharge
- Swelling of the face, mouth, eyes, or lips
- Chills, an increase in body temperature
- A change in the way you walk
- Feeling thirsty, feeling unwell, chest discomfort, feeling «out of sorts», discomfort
- Increased liver transaminases in your blood, increased GGT (a

Common side effects (may affect up to 1 in 10 people):

- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu
- Raised levels of a hormone called «prolactin» found in a blood test (which may or may not cause symptoms). Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods or other problems with your cycle or fertility problems.
- Weight increased, increase appetite, decreased appetite.
- Sleep disorder, Irritability, depression, anxiety, restlessness
- Dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw.
- Dizziness
- Dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching.
- Tremor (shaking)
- Blurry vision, eye infection or «pink eye»
- Rapid heart rate, high blood pressure, shortness of breath
- Sore throat, cough, nosebleeds, stuffy nose
- Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhea, indigestion, dry mouth, toothache
- Rash, skin redness
- Muscle spasms, bone or muscle ache, back pain, joint pain
- Incontinence (lack of control) of urine
- Swelling of the body, arms or legs, fever, chest pain, weakness, fatigue (tiredness), pain
- Fall.

Uncommon side effects (may affect up to 1 in 100 people):

- Infection of the breathing passages, bladder infection, eye infection, tonsillitis, fungal infection of the nails, Infection of the skin, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites
- Decrease in the type of white blood cells that help to protect you against infection, white blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), anemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood
- Allergic reaction
- Diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- Weight loss, loss of appetite resulting in malnutrition and low body weight

11. Side/adverse effects:

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following uncommon side effects (may affect up to 1 in 100 people):

- Have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke
- Experience tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Risperidone may be needed

Tell your doctor immediately if you experience any of the following rare side effects (may affect up to 1 in 1000 people):

- Experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome"). Immediate medical treatment may be needed
- Are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed
- Experience severe allergic reaction characterized by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure.
- Coma due to uncontrolled diabetes
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood
- Yellowing of the skin and the eyes (jaundice)

Tell your doctor immediately if you experience any of the following very rare side effects (may affect up to 1 in 10000 people):

- Life threatening complications of uncontrolled diabetes

The following other side effects may also happen:

Very common side effects (may affect more than 1 in 10 people):

- Difficulty falling or staying asleep.
- Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement «freezing up» and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face
- Feeling sleepy or less alert
- Headache

Method of administration:

FOR ORAL USE.

The solution comes with a syringe (pipette). This should be used to help you measure the exact amount of medicine you need.

Follow these steps:

The bottle comes with a child-resistant cap, and should be opened as follows:

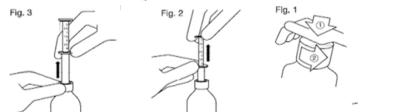


Figure 1:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

Figure 2:

- Inert the pipette into the bottle. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of ml or mg you need to give.

Figure 3:

- Holding the bottom ring, remove the entire pipette from the bottle. Empty the pipette into low-fat milk, orange juice, water, or coffee, by sliding the upper ring down.

Close the bottle. Rinse the pipette with some water.

10. Overdose:

If you take more Risperidone Sugar Free Oral Solution than you should:

- See a doctor right away. Take the medicine pack with you.
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

- If you forget to take Risperidone Sugar Free Oral Solution:

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If you stop taking Risperidone Sugar Free Oral Solution:

You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days.

Adults

- Your starting dose will usually be 2 mg once a day.
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment.
- Most people feel better with doses of 1 to 6 mg once a day.

Elderly people

- Your starting dose will usually be 0.5 mg twice a day.
- Your dose may then be gradually adjusted by your doctor to 1 mg or 2 mg twice a day depending on how you respond to the treatment.
- **For the treatment of long-standing aggression in people with Alzheimer's dementia**

Adults (including elderly people):

- Your starting dose will normally be 0.25 mg twice a day.
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment.
- Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day.
- Treatment duration in patients with Alzheimer's dementia should be not more than 6 weeks.
- **Use in children and adolescents:**
- Children and adolescents under 18 years old should not be treated with Risperidone Sugar Free Oral Solution for schizophrenia or mania.

- For the treatment of conduct disorder

The dose will depend on your child's weight:

For children who weigh less than 50 kg:

- The starting dose will normally be 0.25 mg (0.25 ml of Risperidone oral solution 1 mg/ml) once a day.
- The dose may be increased every other day in steps of 0.25 mg per day.
- The usual maintenance dose is 0.25 mg to 0.75 mg (0.25 ml to 0.75 ml of Risperidone oral solution 1 mg/ml) once a day.

For children who weigh 50 kg or more:

- The starting dose will normally be 0.5 mg once a day.
 - The dose may be increased every other day in steps of 0.5 mg per day.
 - The usual maintenance dose is 0.5 mg to 1.5 mg once a day.
- Treatment duration in patients with conduct disorder should be not more than 6 weeks.

Children under 5 years old should not be treated with Risperidone Sugar Free Oral Solution for conduct disorder.

If you have kidney or liver problems, regardless of the disease to be treated, all starting doses and following doses of Risperidone should be halved. Dose increases should be slower in these patients. Risperidone should be used with caution in this patient group.

- Itraconazole and ketoconazole (medicines for treating fungal infections)
 - Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
 - Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm.
 - Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.
- If you start or stop taking such medicines you may need a different dose of Risperidone.

8. Pregnancy, breast-feeding and fertility:

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will decide if you can take it.
- The following symptoms may occur in newborn babies, of mothers that have used Risperidone Sugar Free Oral Solution in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

• Fertility

As with other drugs that antagonize dopamine D2 receptors, Risperidone elevates prolactin level. Hyperprolactinaemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients that may impact fertility.

9. Dosage & administration:

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is as the follow:

- For the treatment of schizophrenia

Adults

- The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day.
- Your dose may then be adjusted by your doctor depending on how you respond to the treatment.
- Most people feel better with daily doses of 4 to 6 mg.
- This total daily dose can be divided into either one or two doses a day. Your doctor will tell you which is the best for you.

Elderly people

- Your starting dose will normally be 0.5 mg twice a day.
- Your dose may then be gradually increased by your doctor to 1 mg to 2 mg twice a day. Your doctor will tell you which is the best for you.

- For the treatment of mania

sugar Free Oral Solution if:

- You have a heart problem for example an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. Risperidone may cause low blood pressure. Your dose may need to be adjusted.
- You know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain.
- You have ever experienced involuntary movements of the tongue, mouth and face.
- You have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- You have Parkinson disease or dementia.
- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- You are diabetic
- You have epilepsy
- You have kidney problems
- You are a man and you have ever had a prolonged or painful erection
- You have problems controlling your body temperature or overheating
- You have liver problems
- You have an abnormally high level of the prolactin hormone in your blood or if you have a possible prolactin-dependent tumor.
- You or someone else in your family has a history of blood clots, as antipsychotics have been with formation of blood clots.

Effects on ability to drive and use machines:

Risperidone can have minor or moderate influence on the ability to drive and use machines due to potential nervous system and visual effects. Therefore, patients should be advised not to drive or operate machinery until their individual susceptibility is known.

7. Drug interactions:**The following medicines may reduce the effect of Risperidone:**

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines you may need a different dose of Risperidone.

The following medicines may increase the effect of Risperidone:

- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants.
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazine (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

Generic Name: Risperidone

1. Description:

Amber glass bottle with a plastic child-resistance closure containing 120 ml oral solution.

2. Category:

Risperidone is in a class of medications called atypical antipsychotics.

3. Guidance for proper use:

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects. Talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (see section 11)

4. Indications:

Bipolar mania:

Monotherapy (adults and children) - For the short-term treatment of acute manic or mixed episodes associated with bipolar disorder in adults and in children and adolescents 10 to 17 years of age. Combination therapy (adults) - The combination of Risperidone with lithium or valproate is indicated for the short-term treatment of adults with acute manic or mixed episodes associated with bipolar I disorder.

Irritability associated with autistic disorder (children):

For the treatment of irritability associated with autistic disorder in children and adolescents 5 to 16 years of age, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods.

Schizophrenia:

Adults - For the acute and maintenance treatment of schizophrenia:
Adolescents - For the treatment of schizophrenia in adolescents 13 to 17 years of age.

5. Contraindications:

Do not take Risperidone sugar free oral solution:

- If you are allergic to Risperidone or any of the other ingredients of this medicine. (listed in section 13)

6. Warnings and precautions:

This medicine contains benzoic acid. Benzoic acid/Benzoates salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Talk to your doctor or pharmacist before taking Risperidone



Risperidone

1mg/ml

120ml Oral Solution

Each ml contains

Risperidone 1 mg

120 ml

Sugar Free



SINA
PISHGAM
DAROU NOVIN

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