

PACKAGE LEAFLET: INFORMATION FOR THE USER**Rubrum[®] 1, 2, 3, 4, & 6 mg film-coated tablets**
risperidone

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.
- If you have any further questions, ask your doctor or pharmacist.
- 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 doctor or pharmacist or any health care professional or report it to National Medicines Organization (284 Mesogeion Av. 15562, Cholargos - Greece, www.eof.gr).

What is in this leaflet

1. What **Rubrum[®]** is and what it is used for
2. What you need to know before you take **Rubrum[®]**
3. How to take **Rubrum[®]**
4. Possible side effects
5. How to store **Rubrum[®]**
6. Content of the pack and other information

1. WHAT RUBRUM[®] IS AND WHAT IT IS USED FOR

Rubrum[®] belongs to a group of medicines called “anti-psychotics”.

Rubrum[®] is used to treat the following:

- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious or confused.
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called “bipolar disorder”.
- Short-term treatment (up to 6 weeks) of long-term aggression in people with Alzheimer’s dementia, who harm themselves or others. Alternative (non-drug) should have been used previously.
- Short-term treatment (up to 6 weeks) of long-term, aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RUBRUM[®]**Do not take Rubrum[®]**

- If you are allergic (hypersensitive) to risperidone or any of the other ingredients of **Rubrum[®]** (listed in section 6).
- If you are not sure that your condition is not included in the above listed, talk to your doctor or pharmacist, before you use **Rubrum[®]**.

Warnings and precautions for Rubrum[®]

Talk to you doctor or pharmacist before you take **Rubrum[®]** if:

- You have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. **Rubrum[®]** may cause low blood pressure. Your dose may need to be adjusted.
- You know of any factors which would favor you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain.
- You have Parkinson’s disease or dementia.
- You are diabetic.

- You have epilepsy.
- You are a man and you have a prolonged or painful erection. If you experience this while you take **Rubrum**[®], consult your doctor immediately.
- You have problems controlling your body temperature or overheating.
- You have kidney problems.
- You have liver problems.
- You have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumor.

Talk to your doctor immediately in case you experience any of the following:

- Involuntary movements of the tongue, mouth and face. You may need to stop risperidone.
- Symptoms that include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome). You may need immediate medical care.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using **Rubrum**[®].

Rubrum[®] may cause you to gain weight.

Elderly people with dementia

In elderly patients with dementia, there is an increased risk of stroke.

You should not take risperidone if you have dementia caused by stroke.

During treatment with risperidone you should frequently see your doctor.

Medical treatment should be sought straight away if you or your care-giver notice 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.

Children and adolescents

Before treatment is started for conduct disorder, other causes of aggressive behavior should have been ruled out.

If during treatment with risperidone tiredness occurs, a change in the time of administration might improve attention difficulties.

Other medicines and Rubrum[®]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those that you get from the pharmacy without prescription or herbal medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines to treat raised blood pressure. **Rubrum**[®] can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build up of too much fluid (such as furosemide or chlorothiazide). **Rubrum**[®] taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone:

- Rifampicin (a medicine for treating 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)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

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

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using **Rubrum[®]**.

Rubrum[®] with food, drink and alcohol

You can take this medicine with or without food. You should avoid drinking alcohol when taking **Rubrum[®]**.

Pregnancy and breast feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before you take **Rubrum[®]**. Your doctor will decide if you can take it.
- The following symptoms may occur in newborn babies, of mothers that have used risperidone during the last trimester (last three months of pregnancy), shaking, muscle stiffness and sensory problems, which are all reversible.

Ask your doctor or pharmacist for advice before you take any medicine.

Driving and using machines

Dizziness, tiredness and vision problems may occur during treatment with **Rubrum[®]**. Do not drive or use any tools or machines without talking to your doctor first.

Important information about some excipients of Rubrum[®]

Rubrum[®] film-coated tablets contain lactose, a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Rubrum[®] film-coated tablets of 2 mg and 6 mg contain Sunset yellow E110, which may cause allergic reactions.

3. HOW TO TAKE RUBRUM[®]

How much you should take. The recommended dose is as follows:

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 wither one or two doses a day. Your doctor will tell you which is preferable 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 preferable for you.

Children and adolescents

- Children and adolescents under 18 years of age should not be treated with **Rubrum®** for schizophrenia.

For the treatment of mania**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 to 2 mg twice a day depending on how much you respond to the treatment.

Παιδιά και έφηβοι

- Children and adolescents under 18 years of age should not be treated with **Rubrum®** for mania.

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.

For the treatment of conduct disorder in children and adolescents

The dose will depend on your child's weight:

For children weigh less than 50kg

- The starting dose will normally be 0.25 mg 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 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 **Rubrum®** for conduct disorder.

People with 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.

How to administer Rubrum®

Always take **Rubrum®** exactly as your doctor has instructed. If you have doubts ask your doctor or pharmacist.

Your doctor will tell you how much medicine you should take and for how long. This will depend on your condition and varies from person to person. The quantity you should take is described under the title “**How much you should take**”.

You should swallow **Rubrum**[®] film-coated tablet with a drink of water.

If you take more Rubrum[®] 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 Rubrum[®]

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 Rubrum[®]

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Very common:	may affect more than 1 in 10 people
Common:	may affect 1 to 10 people out of 100
Uncommon:	may affect 1 to 10 people out of 1.000
Rare:	may affect 1 to 10 people out of 10.000
Very Rare:	may affect less than 1 person out of 10.000
Unknown:	frequency cannot be estimated from the available data

The following side effects may happen:

Very common

- 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.
- Headache
- Difficulty falling or staying asleep.

Common

- Dullness, fatigue, anxiety, lack of ability to stay seated at one point, irritation, stress, drowsiness, dizziness, lack of attention, feeling exhausted, sleep disorder, tremor.
- Vomiting, diarrhea, constipation, nausea, increased appetite, abdominal pain or discomfort, sore throat, dry mouth.
- Increased body weight, increased body temperature, decreased appetite.
- Difficulty breathing, Lung infection (pneumonia), flu-like symptoms, respiratory tract infection, blurry vision, sinus infection, nose bleeds, cough.
- Urinary tract infection, loss of urine during sleeping.

- Muscle spasms, involuntary movements of the face or hands and feet, Joint pain, Back pain, Swelling of arms and legs, Pain in arms and legs.
- Rash, skin redness.
- Rapid heart rate, Chest pain.
- Raised levels of a hormone called "prolactin" found in a blood test (which may or may not cause symptoms).

Uncommon

- Excessive water consumption, fecal incontinence, thirst, very hard stools, hoarseness or voice disorders.
- Lung infection caused by inhaling food into respiratory tract, bladder infection, conjunctivitis, vaginal infection, viral infection, ear infection, infection of the tonsils, infection under the skin, eye infection, stomach infection, eye discharge, fungal infection of the nails.
- Abnormal electrical conduction of the heart, decrease in blood pressure upon standing, low blood pressure, abnormal electrical tracing of the heart (electrocardiogram or ECG), abnormal heart rate, palpitations, increased or decreased heart rate.
- Frequent passing of urine, inability to pass urine, pain when passing urine.
- Confusion, disturbance in attention, low levels of consciousness, excessive sleep, agitation, elated mood (mania), lack of energy and interest.
- High blood sugar, increased levels of liver enzymes, decreased number of white blood cells, decreased levels of hemoglobin or decreased number of red blood cells (anemia), increased number of eosinophil cells (specific leukocytes), increased blood levels of creatine phosphokinase, reduced levels of platelets (blood cells that help to stop bleeding).
- Muscle weakness, muscle pain, ear pain, neck pain, swollen joints, abnormal posture, stiffness of joints, musculoskeletal pain in the chest, chest discomfort.
- Skin lesion, skin disorder, dry skin, intense itching, acne, hair loss, skin infection caused by mites, discoloration, thickening of the skin, flushing, reduced skin sensation to pain and touch, inflamed oily skin.
- Discontinuation of menstruation, sexual dysfunction, erectile dysfunction, failure to ejaculate, breast discharge, breast swelling in men, decreased libido, irregular menstruation, vaginal discharge.
- Fainting, impaired walking, listlessness, decreased appetite that leads to poor nutrition and low body weight, bad mood, balance disorder, allergy, edema, διάθεση, διαταραχή ισορροπίας, αλλεργία, οίδημα, speech disorders, tremors, abnormal coordination.
- Painful hypersensitivity to light, increased blood flow to the eye, eye swelling, dry eye, increased tears.
- Respiratory disorder, lung congestion, crackly lung sounds, congestion of breathing passages, voice disorders, difficulty swallowing, cough with sputum, gruff/hissing sound during breathing, influenza-like syndrome, sinus congestion.
- Non-responsiveness to stimuli, loss of consciousness, sudden swelling of the lips and of the eyes along with shortness of breath, sudden weakness or numbness of the face, arms or legs, especially on one side of the body or incidents of poor articulation of speech lasting less than 24 hours (these are called mini strokes or strokes), involuntary movements of the face, hands or feet, buzzing in ears, facial swelling.

Rare

- Inability to reach orgasm, menstrual disorders.
- Dandruff.
- Severe allergic reaction, coldness in arms and legs, swollen lips, inflammation on the lips.
- Glaucoma decreased visual clarity, eyelid margin crusting, eye rolling.
- Lack of emotion
- Alterations of consciousness, increased body temperature and muscle contractions, swelling of the whole body, withdrawal syndrome, decreased body temperature.
- Fast shallow breathing, trouble breathing during sleep.
- Blockage in the bowels.
- Decreased blood flow to the brain.

- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood.
- Breakdown of muscle fibers and chest pain (rhabdomyolysis), irregular movements.
- Coma due to uncontrolled diabetes.
- Yellowing of the skin and eyes (jaundice).
- Inflammation of the pancreas.

Very rare:

- Life threatening complications of uncontrolled diabetes.

Unknown

- Serious allergic reaction resulting in difficulty breathing and shock.
- No granulocytes (type of white blood cells that help you against infections).
- Prolonged and painful erection.
- Dangerously excessive intake of water

If you get any side effect, please contact your doctor or pharmacist or any other healthcare professional or directly to National Medicines Agency (284 Mesogion Av., 15562, Chologos, www.eof.gr)

5. HOW TO STORE RUBRUM®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton or bottle. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Rubrum® contains**

The active substance is risperidone.

Each **Rubrum®** film-coated tablet contains 1 mg, 2 mg, 3 mg, 4 mg or 6 mg of risperidone.

The other ingredients are:

Lactose monohydrate, Maize starch, Cellulose microcrystalline, Hypromellose, Sodium lauryl sulphate, Silica colloidal anhydrous, Magnesium stearate, Propylene glycol, Titanium dioxide, Purified Talc.

Film-coated tablets of 2 mg contain also Sunset yellow (E110).

Film-coated tablets of 3 mg contain also Quinoline yellow (E104).

Film-coated tablets of 4 mg contain also Indigotine disulphonate (E132), Quinoline yellow (E 104).

Film-coated tablets of 6 mg contain also Quinoline yellow (E104), Sunset yellow (E110).

What Rubrum® looks like and contents of the pack

- **Rubrum**[®] film-coated tablets of 1 mg are white, biconvex and oblong, with a score line in one side.
- **Rubrum**[®] film-coated tablets of 2 mg are orange, biconvex and oblong, with a score line in one side.
- **Rubrum**[®] film-coated tablets of 3 mg are pale yellow, biconvex and oblong, with a score line in one side.
- **Rubrum**[®] film-coated tablets of 4 mg are green, biconvex and oblong, with a score line in one side.
- **Rubrum**[®] film-coated tablets of 6 mg are yellow, biconvex and oblong with a score line in one side.

1/2/3/4/6 film-coated tablets

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The following pack sizes are available for **Rubrum**[®] 1 mg, 2 mg, 3 mg 4 mg and 6 mg film-coated tablets: Package containing 20 or 30 or 60 film-coated tablets in PVC/LDPE/PVDC aluminum blisters and a leaflet.

Not all pack sizes may be marketed.

Marketing Authorization Holder

TARGET PHARMA Ltd., 54 Menandrou st, 104 31 Athens Greece, Tel.: +30 210 5224830, Fax: +30 210 5224838, Email: info@targetpharma.gr, <http://www.targetpharma.gr>

This leaflet was last revised on 14-12-2012.