PATIENT INFORMATION LEAFLET

Scheduling Status: S5

PMI RISPERIDONE 1 mg/ml (Oral solution):

Risperidone

Sugar free

Preservative: Benzoic Acid 0,15 % *m/v*

Please read this leaflet carefully before you start taking PMI RISPERIDONE 1 mg/ml

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What PMI RISPERIDONE 1 mg/ml contains

PMI RISPERIDONE 1 mg/ml contains active ingredient risperidone, which belongs to the class of medicine called atypical antipsychotics.

PMI RISPERIDONE 1 mg/ml is indicated for:

- Schizophrenia, where you may hear voices, see things, or sense things that are not there, believe things that are not true or feel unusually suspicious or confused.
- Behavioural disturbances in patients with dementia who may have symptoms such as aggressiveness, verbal outbursts, physical violence, agitation and slow or pointless movement.
- Mania in bipolar disorder. These episodes are characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement, including disruptive or aggressive behaviour.
- Children (aged 5 – 12 years) with lower-than-average intellectual functioning or mental retardation that show antisocial and destructive behaviour, including violence towards people and animals, destruction of property, lying, stealing, running away from home, being impulsive and wanting to cause injury to themselves.

2. What you need to know before you take PMI RISPERIDONE 1 mg/ml

Do not take PMI RISPERIDONE 1 mg/ml:

- If you are hypersensitive (allergic) to risperidone or any of the other ingredients of PMI RISPERIDONE 1 mg/ml (listed in section 6).
- Do not give this medicine to children under 5 years with conduct and other disruptive behaviour disorders.
- If you suffer from a type of dementia called Lewy body dementia and Parkinson's disease.

Warnings and precautions

Tell your doctor or health care provider before you take PMI RISPERIDONE 1 mg/ml oral solution:

- If you suffer from kidney or liver function impairment.
- If you experience any signs of possible Tardive dyskinesia (TD) such as sudden uncontrollable movements of voluntary muscle groups. Signs can consist of coordinated, constant movements of the mouth, tongue, jaw and cheeks and in some cases movement in your arms and legs. The risk of developing TD and the chance that it will become permanent is thought to increase with the length of therapy and the overall dose taken by the patient. This condition can develop after a brief period of therapy at low doses, although this is much less common. There is known treatment for TD, but it may go away partially or completely if therapy is stopped.
- If you experience any signs of Neuroleptic Malignant Syndrome (NMS) which is a potentially serious side effect reported with PMI RISPERIDONE 1 mg/ml which may cause death. Signs may include that your muscles are constantly tense, your body temperature is very high, shaking, confusion, sweating, your heart beats very rapidly or blood pressure or muscle pain and weakness. Treatment with PMI RISPERIDONE 1 mg/ml should be stopped immediately if you have NMS.
- If you know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder, current smoking or blood vessel problems in the brain or if you are older than 80 years
- If you experience signs of cerebrovascular adverse events, such as a stroke. Signs may include that you cannot move or feel one side of your body, you may be confused and have difficulty to say words and follow commands.

- If you suffer from epilepsy (a condition causing seizures). PMI RISPERIDONE 1 mg/ml may worsen the symptoms of this condition.
- If you have a heart problem. Examples include an irregular heart rhythm, or if you are prone to low blood pressure. PMI RISPERIDONE 1 mg/ml may cause low blood pressure due to its alpha blocking activity. Your dose needs to be adjusted.
- If you are using a water tablet (diuretic) called furosemide. Studies have shown that older adults with dementia who are treated with furosemide and PMI RISPERIDONE 1 mg/ml are at an increased risk of death when compared to patients being treated with only PMI RISPERIDONE 1 mg/ml. Drink plenty of fluids, especially in hot weather and avoid becoming dehydrated while you are taking this medication.
- If you have an abnormally high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependant on prolactin. PMI RISPERIDONE 1 mg/ml commonly raises levels of prolactin. This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see section 4). If such side effects occur, evaluation of the prolactin level in blood is recommended.
- If you have or think you might have diabetes. As diabetes mellitus or worsening of pre-existing diabetes mellitus has been seen in patients taking PMI RISPERIDONE 1 mg/ml, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly.
- If you have abnormally high levels of blood sugar. Signs may include frequently feeling very hungry and or thirsty, urinating frequently, blurred vision, sleepiness and dry mouth.
- If you have problems maintaining your weight. This medicine may cause you to gain weight. Significant weight gain can adversely affect your health. Your doctor should regularly measure your body weight. Avoid overeating.
- If you are a man and you have ever had prolonged or painful erection.

- If you have problems controlling your body temperature or overheating.
- If you or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.
- If you are planning to have an operation on your eye, make sure you tell your doctor that you are taking PMI RISPERIDONE 1 mg/ml. During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage.
- If 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). Your doctor may check your white blood cell counts.
- If you have a brain tumor, intestinal obstruction or Reye's syndrome (a serious condition that causes swelling in the liver and brain).

Elderly people with dementia

In elderly patients with dementia, there is an increased risk of stroke. You should not take PMI RISPERIDONE 1 mg/ml if you have dementia caused by stroke.

Medical treatment should be sought straight away if you or your caregiver 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.

During treatment with PMI RISPERIDONE 1 mg/ml you should frequently see your doctor.

Children and adolescents

PMI RISPERIDONE 1 mg/ml should be used with caution in young children and adolescents with conduct disorder. Before treatment is started for conduct disorder, other causes of aggressive

behaviour should have been ruled out. If PMI RISPERIDONE 1 mg/ml has been prescribed for your child, inform your doctor if you notice that your child is tired or sleepy as this may impact learning ability.

A change in the time of administration might improve attention difficulties.

Before treatment is started your child's body weight may be measured, and it may be regularly monitored during treatment.

Using other medicines with PMI RISPERIDONE 1 mg/ml

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

The following medicine may reduce the effect of PMI RISPERIDONE 1 mg/ml

- Carbamazepine, phenytoin, phenobarbital (medicines for treating epilepsy)
- Clozapine (medicine for treating schizophrenia)
- Rifampicin (a medicine for treating some infections)

The following medicine may increase the effect of PMI RISPERIDONE 1 mg/ml

- Antidepressants such as fluoxetine and paroxetine as well as venlafaxine and tricyclic antidepressants
- Cimetidine and ranitidine (medicine for treating heartburn or stomach ulcers)
- Medicines known as beta-blockers (for the treatment of high blood pressure)
- Phenothiazines (e.g. used to treat psychosis or to calm down)
- Quinidine (used for certain types of heart disease)
- 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.

It is very important to tell your doctor, pharmacist or healthcare provider if you take any of the following:

- Water tablets (diuretics) used to treat certain heart problems or swelling of body parts due to build up of too much fluid such as furosemide (refer to "Warnings and precautions")
- Alcohol or medicines that work on your brain such as medicines to calm you down (benzodiazepines), some medicines for pain (opiates), medicines for allergies (certain antihistamines) as PMI RISPERIDONE 1 mg/ml may increase the sedative effect of them all.
- Medicines that may change the electrical activity of your heart, such as medicines for malaria (such as quinidine and mefloquine), heart rhythm problems (such as amiodarone, quinidine), allergies (antihistamines), some antidepressants (such as amitriptyline, maprotiline) or other medicines for mental problems
- Medicines that cause a slow heartbeat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)
- Lithium (used to treat certain types of depression)
- Medicines to treat Parkinson's disease such as levodopa
- Valproate (used to treat epilepsy and seizures)

- Topiramate (medicine used to treat epilepsy) does not have a significant effect on the level of PMI RISPERIDONE 1 mg/ml in the blood.
- Medicines to lower your blood pressure
- Paliperidone (a medicine used to treat mental disorders including schizophrenia)
- Erythromycin (an antibiotic) does not have an effect on level of PMI RISPERIDONE 1 mg/ml in the blood.
- Galantamine and donezepil (medicines used to treat dementia) do not have an effect on PMI RISPERIDONE 1 mg/ml.

PMI RISPERIDONE 1 mg/ml with food and drink and alcohol

Taking alcohol during treatment with PMI RISPERIDONE 1 mg/ml may have additive CNS depressant effects. PMI RISPERIDONE 1 mg/ml can be taken with or without food.

Pregnancy and breastfeeding and fertility

The safety of PMI RISPERIDONE 1 mg/ml in pregnant and breast-feeding women has not yet been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking PMI RISPERIDONE 1 mg/ml.

Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding, have been observed in newborns, if a mother used PMI RISPERIDONE 1 mg/ml in the last trimester of her pregnancy.

Driving and using machinery

PMI RISPERIDONE 1 mg/ml may cause sleepiness and a lack of concentration. It is not always possible to predict to what extent PMI RISPERIDONE 1 mg/ml may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PMI RISPERIDONE 1 mg/ml affects them.

PMI RISPERIDONE 1 mg/ml contains benzoic acid

PMI RISPERIDONE 1 mg/ml contains 1,50 mg of benzoic acid in each ml of oral solution. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take PMI RISPERIDONE 1 mg/ml

Do not share medicines prescribed for you with any other person.
Always take PMI RISPERIDONE 1 mg/ml exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of PMI RISPERIDONE 1 mg/ml is too strong or too weak, talk to your doctor or pharmacist.

Treatment of schizophrenia

If you are already using an antipsychotic medicine, your doctor may gradually discontinue this treatment when switching to PMI RISPERIDONE 1 mg/ml. If you are receiving a depot injection, your doctor will initiate PMI RISPERIDONE 1 mg/ml treatment in place of the next scheduled injection.

You may take PMI RISPERIDONE 1 mg/ml either once daily or twice daily.

Initial adult dose: The usual dose is 2mg per day. Your doctor may increase the dosage to 4mg per day on the second day.

Maintenance dose: Your doctor will decide what the optimum maintenance dose is based on your response.

Liver and kidney impairment:

Your doctor should halve both the starting dose and the subsequent dosage increases if you suffer for liver or kidney impairment.

Elderly patients:

The starting dose is usually 0,5 mg twice daily. Your doctor may increase the dose up to 1 – 2 mg twice daily.

Children:

PMI RISPERIDONE 1 mg/ml should not be used in children under the age of 15 years.

Treatment of mania in bipolar disorders

The starting dose will normally be 2 mg once a day and your dose may gradually be adjusted by your doctor depending on how you respond to the treatment. Efficacy was demonstrated in flexible doses over a range of 1 mg to 6 mg per day.

Treatment of behavioural disturbances in patients with dementia

The usual starting dose is 0,25 mg twice daily. Your doctor may increase the dose to a maintenance dose of 0,5 mg to 1 mg twice daily.

Treatment of conduct and other disruptive behaviour disorders in children 5 – 12 years of age

A doctor only will decide this treatment and dosage. The usual starting dose is 0,01 mg per kg once daily. The doctor may increase the dose to a maintenance dose of 0,02 – 0,04 mg per kg once daily.

Children under 5 years old should not be treated with PMI RISPERIDONE 1 mg/ml for conduct and disruptive behaviour disorders.

DIRECTIONS FOR OPENING THE BOTTLE AND USING THE PIPETTE

1. Push the plastic screw cap down while turning it counter clockwise. Remove the unscrewed cap.
2. Insert the pipette into the bottle. While holding down the barrel, pull the plunger up to the level that corresponds with the dosage required for administration.
3. While holding the plunger, remove the pipette from the bottle.
4. Empty the pipette into any non-alcoholic drink, except for tea, by sliding the plunger down.
5. Close the bottle and rinse the pipette.

If you take more PMI RISPERIDONE 1 mg/ml than you should

In the event of overdose, one or more of the following symptoms may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medications together with PMI RISPERIDONE 1 mg/ml.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the remaining solution and/or the container with you to the hospital so that the doctor knows what you have taken. There is no specific antidote for risperidone overdose.

If you forget to take PMI RISPERIDONE 1 mg/ml

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the solution at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking PMI RISPERIDONE 1 mg/ml

You should not stop taking PMI RISPERIDONE 1 mg/ml unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop PMI RISPERIDONE 1 mg/ml, your dose may be decreased gradually over a few days.

4. Possible side effects

PMI RISPERIDONE 1 mg/ml can cause side effects. Not all side effects reported for PMI RISPERIDONE 1 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PMI RISPERIDONE 1 mg/ml, please consult your health care provider for advice.

If any of the following happen, stop taking PMI RISPERIDONE 1 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Fast or irregular heart beat

- Difficult or unusually fast breathing, high fever, irregular blood pressure, loss of bladder control, severe muscle stiffness, seizures, unusual pale skin, tiredness or weakness, could be signs of Neuroleptic Malignant Syndrome.
- Cough difficulty swallowing, dizziness, hives, itching, tightness in chest, wheezing and puffiness or swelling of eyelids, face, lips or tongue.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PMI RISPERIDONE 1 mg/ml. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- angina;
- 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;
- 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 sudden loss of blood supply to the brain (stroke or “mini” stroke);
- are a man and experience prolonged or painful erection. This is called “priapism”. Immediate medical treatment may be needed
- 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 PMI RISPERIDONE 1 mg/ml may be needed;

- signs of recurrent infections such as fever or sore throat;
- fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing, signs of agranulocytosis
- less urine than is normal for you;
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu;
- Anxiety;
- Muscle spasm of face, neck and back, twitching movements, weakness of arms or legs (Parkinsonism);
- Difficulty in speaking or swallowing, loss of balance control, trembling and shaking of hands and fingers; tremor
- Insomnia (sleeplessness); weakness; fatigue; lassitude; drowsiness; headache; increased dream activity; increased duration of sleep;
- Changes in vision and blurred vision, inflammation of the eye “pink eye”;
- Rapid heart rate and high blood pressure;
- Shortness of breath, cough, sore throat, nose bleeds, stuffy nose, pain in the throat;

- Constipation, diarrhoea; dyspepsia; vomiting; nausea, abdominal pain, dry mouth, stomach discomfort, toothache;
- Skin rash or itching, redness;
- Problems in urination or increase in amount of urine;
- Weight gain, increased appetite or decreased appetite;
- Mood or mental changes, including aggressive behaviour, agitation, difficulty in concentration and memory problems.
- Unusual secretion of milk; sexual dysfunction or decrease libido; menstrual changes.
- Back pain, joint pain, muscle spasms, pain in the muscles and bones, pain in extremity;
- falls
- Swelling of the body, arms or legs, fever, chest discomfort, weakness, fatigue (tiredness), pain;
- PMI RISPERIDONE 1 mg/ml can raise your levels of a hormone called "prolactin" found on a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include in men breast swelling, difficulty in getting or maintaining erections, 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.

Less frequent side effects:

- 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; ear infection and chronic ear infection;

- Decrease in the type of white blood cells that help to protect you against infection, white blood cell counts decreased, decrease in platelets (blood cells that help you stop bleeding), anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood;
- Confusion, decreased sexual drive, listless, nervousness, delayed orgasm, elated mood (mania) or depressed mood (hypomania), nightmares, sleep walking, sleep related eating disorder;
- 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 of skin;
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes;
- Glaucoma (increased pressure within the eyeball), eye rolling, eye movement disorder, eyelid margin crusting;
- Eye problem during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken PMI RISPERIDONE 1 mg/ml. If you need to have cataract surgery, be sure to tell your doctor if you take or have taken PMI RISPERIDONE 1 mg/ml.
- 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 PMI RISPERIDONE 1 mg/ml may feel faint, dizzy, or may pass out when they stand 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;
- Trouble breathing during sleep (apnoea), fast, shallow breathing;
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind;
- Inflammation of the pancreas, a blockage in the bowels, swollen tongue, chapped lips; gastroenteritis “stomach bug”, decreased contraction of the intestines (ileus)
- Hives (or "nettle rash"), itching, hair loss, thickening of skin, eczema, dry skin, skin discolouration, acne, dandruff, skin disorder, skin lesion, increased sweating, skin discoloration, rash on skin related to a drug, dandruff;
- Frequent passing of urine, inability to pass urine, pain when passing urine;
- Symptoms of medicine withdrawal including in newborns
- 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 discomfort, vaginal discharge, breast enlargement, breast discharge;
- Inappropriate secretion of a hormone that controls urine volume;
- Diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- Dangerously excessive intake of water, increased insulin (a hormone that controls blood sugar levels) in your blood, life threatening complications of uncontrolled diabetes, coma due to uncontrolled diabetes;

- Sugar in the urine, low blood sugar, high blood triglycerides (fats);
- Muscle weakness, muscle pain, neck pain, joint swelling, joint stiffness, abnormal posture increased blood creatinine phosphokinase (seen on a blood test) breakdown of muscle fibres and pain in muscles (rhabdomyolysis);
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood, increased liver enzymes in your blood;
- Swelling of the face, sluggishness, chills, an increase in body temperature, a change in the way you walk, feeling thirsty, feeling unwell, feeling out of sorts, discomfort, hardening of skin;
- Decreased body temperature, coldness in arms and legs;
- Procedural pain.

Frequency unknown side effect

- Reduced visual acuity.

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone (as in RISPIDE), so these can also be expected with RISPIDE: rapid heartbeat upon standing.

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), diarrhoea, and incontinence (lack of control) of urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PMI RISPERIDONE 1 mg/ml.

5. How to store PMI RISPERIDONE 1 mg/ml

- Store at or below 25 °C or below. Do not freeze. Keep well closed.
- Once opened the product can be stored at or below 25 ºC for 100 days.
- KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN
- Do not use the solution after the expiry date printed on the label/container.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What PMI RISPERIDONE 1 mg/ml contains

PMI RISPERIDONE 1 mg/ml contains the active ingredient risperidone. Each 1 ml of oral solution contains 1 mg of risperidone.

Inactive ingredients: Benzoic acid (preservative 0,15 % m/v), hydrochloric acid, tartaric acid and purified water.

What PMI RISPERIDONE 1 mg/ml looks like and contents of the pack

Clear colourless solution free from foreign particles.

30 ml; 60 ml, 100 ml or 120 ml Amber glass bottle (USP Type III) with white Light Density Polyethylene/Polypropylene child resistant, tamper evident cap. Additionally a 4 ml dosing pipette

is supplied in each pack consisting of a polystyrene plunger, Light Density Polyethylene barrel and piston, Light Density Polyethylene protective sheath (dosing pipette holder) and Polyethylene wiper. The dosing pipette is CE "Conformite Europeene" marked. The bottle and dosing pipette are packed in an outer cardboard container

Holder of Certificate of Registration

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