APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have 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.

S5

RUTRA SOLUTION 1 mg/ml (Solution)

Risperidone

1. WHAT RUTRA SOLUTION 1 mg/ml CONTAINS

The active substance is risperidone.

Each ml contains 1 mg risperidone.

Preservative: Benzoic acid……..0.2 %

The other ingredients are hydrochloric acid and purified water.

2. WHAT RUTRA SOLUTION 1 mg/ml IS USED FOR

Risperidone is an antipsychotic medication (medication for mental illness). It works by helping to restore the balance of certain natural substances in the brain called neurotransmitters. Risperidone is used to treat schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions). Risperidone can improve symptoms of behaviour problems in patients with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality). Risperidone is also used to treat behaviour problems which are disruptive / destructive in children (ages 5 – 12 years), with mental retardation.

3. BEFORE YOU TAKE RUTRA SOLUTION 1 mg/ml

Do not take RUTRA SOLUTION 1 mg/ml:

- If you have ever had an unusual or allergic reaction to risperidone or any ingredient of the product.
- If you have Lew antibody dementia.
- **RUTRA SOLUTION 1 mg/ml** should not be given to children under 5 years of age.

Take special care with RUTRA SOLUTION 1 mg/ml:

- Tardive dyskinesia (TD) is a serious, sometimes permanent side-effect reported with **RUTRA SOLUTION 1 mg/ml**. TD includes uncontrollable movements of the face, tongue, and other parts of the body. 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 no known treatment for TD, but it may go away partially or completely if therapy is stopped.
- Neuroleptic Malignant Syndrome (NMS) is a potentially serious side-effect reported with **RUTRA SOLUTION 1 mg/ml** which may cause death. Call your doctor immediately if you develop symptoms such as high fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness. Treatment with **RUTRA SOLUTION 1 mg/ml** should be stopped immediately if you have NMS.
- Tell your doctor if you are taking furosemide (water pill) – Studies have shown that older adults with dementia who are treated with furosemide and **RUTRA SOLUTION 1 mg/ml** are at an increased risk of death when compared to patients being treated with only **RUTRA SOLUTION 1 mg/ml**. Drink plenty of fluids, especially in hot weather and avoid becoming dehydrated while you are taking this medication.
- High blood sugar and diabetes have been reported with **RUTRA SOLUTION 1 mg/ml**. If you have diabetes or risk factors such as being overweight or a family history of diabetes, blood sugar testing should be performed at the beginning and throughout treatment. Complications of diabetes can be serious and even life threatening. If signs of diabetes or high blood sugar develop, such as being thirsty all the time, frequent urination, or feeling weak or hungry, contact your doctor.
- Older adults with dementia may also have a greater chance of having a stroke or mini-stroke during treatment with **RUTRA SOLUTION 1 mg/ml**.
- Tell your doctor if you have Parkinson's disease or dementia with Lewy bodies (DLB) – Patients with either of these conditions may be at increased risk of Neuroleptic Malignant Syndrome (NMS), which

is a serious side-effect reported with **RUTRA SOLUTION 1 mg/ml** that can cause death. Patients may also become confused, be less alert, fall frequently and experience extrapyramidal symptoms (persistent movement disorders or muscle disturbances, such as restlessness, tremors, and muscle stiffness).

- You may feel faint or lightheaded if you stand up or sit up too quickly. This is more common when you first start taking **RUTRA SOLUTION 1 mg/ml**. By standing up or sitting up slowly and following your healthcare professional's dosing instructions, this side-effect may be reduced or go away over time.
- Tell your doctor if you have epilepsy or a seizure disorder – **RUTRA SOLUTION 1 mg/ml** should be used cautiously.
- Tell your doctor if you have liver or kidney disease.
- This medicine may cause you to gain weight. Avoid overeating.

Pregnancy and Breast-feeding:

Do not use this medication without telling your doctor if you are pregnant, think you may be pregnant, or are planning a pregnancy. The safety of this medication in pregnant women has not been established.
Do not use this medication of you are breast-feeding. This is because small amounts may pass into the mother's milk.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

This medicine may make you drowsy. Do not drive or use machinery until you know how this medication affects you.

Taking RUTRA SOLUTION 1 mg/ml with drink:

You should know that alcohol can add to the drowsiness caused by this medication, and make you feel less alert.

Taking other medicines with RUTRA SOLUTION 1 mg/ml:

Before taking **RUTRA SOLUTION 1 mg/ml**, tell your doctor if you are using any of the following medicines:

- Furosemide – Studies in elderly patients have shown that taking **RUTRA SOLUTION 1 mg/ml** with furosemide may be harmful.
- Beta-blockers

- Carbamazepine
- Valproate
- Venlafaxine
- Lithium
- Cimetidine
- Ranitidine
- Medicines for depression such as fluoxetine or paroxetine, and tricyclic antidepressants.
- Medicines for anxiety such as phenothiazines.
- Medicines for Parkinson's disease such as levodopa.

If you are using any of these medicines, you may not be able to take **RUTRA SOLUTION 1 mg/ml**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **RUTRA SOLUTION 1 mg/ml** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE RUTRA SOLUTION 1 mg/ml

- Take this medicine only as directed by your doctor.
- Do not take more or less of it or take it more often than prescribed by your doctor.
- For the treatment of schizophrenia:

  The adult dose is usually taken once or twice a day.

  When you start taking **RUTRA SOLUTION 1 mg/ml**, you will normally take the following amount:

  - 2 mg on the first day.
  - 4 mg on the second day.

  Your **RUTRA SOLUTION 1 mg/ml** dosage you then take will either be maintained or adjusted until your doctor finds the dose that suits you best. This is usually between 4 mg and 8 mg a day.

  If you are elderly, your doctor will start you on a lower dose.
- For the treatment of behavioural problems in adults with dementia:
  - The usual dose you start with is 0.25 mg twice a day.

- Your doctor will adjust this dose if necessary.
- Most patients feel better with a dose of 0.5 mg twice a day.

- For the treatment of behaviour problems in children aged 5 to 12 years:

  The dose for children is based on their body weight, and will be determined by your doctor.

- Patients with liver or kidney problems:

  Your doctor will give you a lower dose.

Always take **RUTRA SOLUTION 1 mg/ml** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **RUTRA SOLUTION 1 mg/ml** is too strong or too weak, talk to your doctor or pharmacist.

If you take more RUTRA SOLUTION 1 mg/ml than you should:

Symptoms of overdose may include drowsiness; fast, pounding, heartbeat; fainting and dizziness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take RUTRA SOLUTION 1 mg/ml:

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE-EFFECTS

RUTRA SOLUTION 1 mg/ml can have side-effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side-effects:

- Changes in your body temperature.
- Seizures.
- Sudden weakness or numbness of the face, arms or legs, especially on one side; slurred speech.

- Jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless. More saliva than normal, twitching or unusual movements of the tongue, face, mouth, jaw or throat.
- High fever; stiff muscles; shaking; confusion; sweating; changes in pulse, heart rate, or blood pressure; or muscle pain and weakness.
- Easy bruising or bleeding.
- Long lasting, painful erection.

Other side-effects include: Weight gain; headache; feeling drowsy, sleepy or tired; runny nose; inability to sleep; anxiety; agitation; difficulty concentrating; dizziness; skin rash; vision problems; constipation; heartburn; nausea; vomiting; abdominal pain; problems with urination; breastmilk production; decreased sexual interest or ability; absence of menstrual periods and an increase in the size of breasts in males.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF RUTRA SOLUTION 1 mg/ml

Store below 30 °C. Do not freeze.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF RUTRA SOLUTION 1 mg/ml

1. Glass bottle:

100 ml solution packed in 125 ml amber coloured, Type III glass bottle, 28 mm neck finish and press in bottle adapter suitable for 28 mm neck, with 28 mm – 400 CR closure with F 217 expanded polyethylene wad.

Pack size: One 125 ml amber coloured glass bottle packed in a printed carton with package insert.

2. HDPE bottle:

100 ml solution packed in 115 ml translucent HDPE container of 28 mm neck finish with 28 mm – 400 CR closure with F 217 expanded polyethylene wad.

Pack size: One 115 ml HDPE container packed in a printed carton with package insert.

8. IDENTIFICATION OF RUTRA SOLUTION 1 mg/ml

A clear, colourless liquid.

9. REGISTRATION NUMBER/REFERENCE NUMBER

41/2.6.5/1056

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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