For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

SYTAS-2 & 3

(Risperidone Tablets USP 2 mg & 3 mg)

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

SYTAS-2 (Risperidone Tablets USP 2 mg)
SYTAS-3 (Risperidone Tablets USP 3 mg)

2. Qualitative and quantitative composition

For 2 mg:
Each uncoated tablet contains:
Risperidone USP 2 mg
For 3 mg:
Each uncoated tablet contains:
Risperidone USP 3 mg
For the full list of excipients, see excipient list section.

3. Pharmaceutical form

Uncoated tablet

4. Clinical particulars

4.1 Therapeutic indications

Risperidone is indicated for the treatment of acute and chronic schizophrenic psychoses and other psychotic conditions in which positive symptoms and/or negative symptoms are prominent. Risperidone also alleviates affective symptoms associated with schizophrenia.

4.2 Posology and method of administration

Risperidone is administered on a twice daily schedule, generally beginning with 1 mg twice daily initially. It is increased in increments of 1 mg twice daily on the second and third day, as tolerated. The usual optional dosage is 2 to 4 mg twice daily. Further dosage adjustment if indicated should generally be made at intervals of not less than one week. In elderly patients and patients with hepatic & renal disease starting dose of Risperidone 0.5 mg is given twice a day. Dosage can be individually adjusted with 0.5 mg twice a day.

4.3 Contraindications

It is contraindicated in patients with known hypersensitivity to benzisoxazole derivatives. Caution should be exercised in patients with cardiovascular diseases, Parkinson's disease, epilepsy, etc.

4.4 Special warnings and precautions for use

If signs and symptoms of tardive dyskinesia appear, therapy should be discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

Risperidone antagonizes the effects of levodopa and other dopamine agonists. It also interacts with phenothiazines, tricyclic antidepressants, beta blockers and the plasma concentration of Risperidone may be increased but not of the antipsychotic fraction.

4.6 Fertility, pregnancy and lactation

Use in pregnancy, lactation & children is not recommended.

4.7 Undesirable effects

Risperidone is generally well tolerated. It causes insomnia, somnolence, fatigue, dizziness, constipation, dyspepsia, nausea, abdominal pain, blurred vision, erectile dysfunction, etc. The incidence and severity of extrapyramidal symptoms are less.

4.9 Overdose

The symptoms of overdosage are drowsiness, sedation, tachycardia, hypotension and extrapyramidal symptoms. There is no specific antidote to Risperidone. Treatment of overdosage is symptomatic and through supportive measures.

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5. Pharmacological properties

Risperidone is a selective monoaminergic antagonist with a high affinity for both serotonergic 5-HT 2 and dopaminergic D2 receptors. Risperidone produces its antipsychotic activity through a combination of dopamine type 2(D2) and serotonin type 2 (5HT2) antagonism. Risperidone is completely absorbed after oral administration, reaching peak plasma concentration within 1 to 2 hours. The absorption is not affected by food. It is metabolized in the liver to 9-hydroxyrisperidone which has a similar pharmacological activity to Risperidone. After oral administration, the elimination half-life of the active antipsychotic fraction is 24 hours. The absolute bioavailability of Risperidone is 70%. It is 70% to 90% plasma protein bound.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose
Maize Starch
Purified Water
Microcrystalline Cellulose (PH102)
Sodium Lauryl Sulphate
Colloidal Anhydrous Silica
Talc
Magnesium Stearate
Colorants:
For 2 mg:
Sunset Yellow Supra
For 3 mg:
Quinoline Yellow

6.2 Shelf life

3 years

6.3 Storage

Store below 30 °C, protected from light and moisture.

6.4 Nature and contents of container

Risperidone Tablets USP 2 mg are packed in Alu - PVC blister pack of 10 tablets and such 5 blisters are packed in 1 carton.
Risperidone Tablets USP 3 mg are packed in Alu - PVC blister pack of 10 tablets and such 5 blisters are packed in 1 carton.

7. Manufactured by:

INTAS

INTAS PHARMACEUTICALS LTD.
Camp Road, Selaqui, Dehradun,
Uttarakhand, India

8. Date of revision of the text

14.05.2018

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Approved
(11/6/2021)

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