# Information For the User Amisulpride 100mg Tablet

# **Sulpide 100 Tablet**

**Brand Name:** Sulpide 100 Tablet

Dosage Form: Tablet

Therapeutic Category: Atypical Antipsychotic

#### **Composition:**

Each film-coated tablet contains:

• Amisulpride IP – 100 mg

• **Excipients** -q.s.

• Colour: Approved colour used

## Pharmacology & Mechanism of Action:

Amisulpride is a selective dopamine D2/D3 receptor antagonist. It exerts antipsychotic activity by blocking postsynaptic dopamine receptors in limbic areas, and at low doses, it blocks presynaptic dopamine autoreceptors, enhancing dopaminergic transmission. This dual mechanism improves both positive and negative symptoms of schizophrenia. It has minimal affinity for serotonin, adrenergic, cholinergic, or histaminergic receptors, leading to fewer side effects such as sedation or weight gain.

#### **Indications:**

- Schizophrenia (both positive and negative symptoms)
- Dysthymia and other mood-related disorders (off-label use under supervision)

# **Dosage & Administration:**

- Dose varies according to condition and severity
- **Typical adult dose:** 100–400 mg/day in divided doses
- For predominantly negative symptoms: 50–300 mg/day
- In acute psychotic states: Higher doses (up to 800–1200 mg/day) may be used
- To be taken orally with or without food, as directed by a physician

#### **Contraindications:**

- Hypersensitivity to Amisulpride
- Pheochromocytoma
- Lactating women
- Children below 18 years (unless specifically advised)

#### **Warnings & Precautions:**

- Use cautiously in patients with renal impairment dose adjustment required
- May prolong QT interval avoid in patients with known cardiac conduction disorders
- Risk of extrapyramidal symptoms at high doses
- May increase serum prolactin levels monitor in long-term therapy
- Not recommended during pregnancy unless absolutely necessary

#### **Drug Interactions:**

• Avoid concurrent use with medications that prolong QT interval (e.g., quinolones, certain antiarrhythmics)

- Caution with CNS depressants and alcohol
- Antihypertensive effects may be enhanced

#### **Adverse Effects:**

- Common: Insomnia, anxiety, weight gain, increased prolactin, extrapyramidal symptoms
- Rare: Tardive dyskinesia, galactorrhea, amenorrhea, QT prolongation, neuroleptic malignant syndrome

#### Overdose:

Symptoms: Drowsiness, sedation, hypotension, extrapyramidal symptoms

Treatment: Supportive care; no specific antidote. Monitor cardiac status and airway support if

required.

## **Storage:**

Store below 25°C in a dry place Protect from light and moisture Keep out of reach of children

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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