Information For the User Amisulpride 200mg Tablet

Sulpide 200 Tablet

Brand Name: Sulpide 200 Tablet

Dosage Form: Tablet

Therapeutic Category: Atypical Antipsychotic – Dopamine D2/D3 Antagonist

Composition:

Each uncoated tablet contains:

- Amisulpride I.P. 200 mg
- Excipients q.s.

Colour: Approved colour used

Pharmacology & Mechanism of Action:

Amisulpride is a selective dopamine D2 and D3 receptor antagonist. At lower doses, it preferentially blocks presynaptic autoreceptors, enhancing dopaminergic transmission and improving negative symptoms of schizophrenia such as social withdrawal, apathy, and blunted affect. At higher doses, it blocks postsynaptic receptors to reduce positive symptoms like hallucinations, delusions, and thought disorders.

Indications:

- Acute and chronic schizophrenia
- Management of both positive and negative symptoms of schizophrenia
- Psychotic disorders with predominant affective components
- Off-label use in dysthymia and bipolar disorder (under supervision)

Dosage & Administration:

The usual adult dose ranges from 400–800 mg per day depending on the severity of symptoms. The 200 mg tablet is typically used in moderate to severe cases or as part of a divided daily regimen. Dose should be adjusted in elderly patients and those with renal impairment. Take before meals. Do not crush or chew.

Contraindications:

- Known hypersensitivity to Amisulpride or any tablet component
- Prolactin-dependent tumors
- Pheochromocytoma
- Severe renal dysfunction
- Co-administration with levodopa

Warnings & Precautions:

Regular monitoring is advised for long-term therapy due to risk of hyperprolactinemia and QT interval prolongation. Use with caution in cardiovascular disease, electrolyte imbalance, or patients predisposed to seizures. Avoid abrupt discontinuation. Not recommended during pregnancy or lactation unless clearly indicated.

Drug Interactions:

Should not be used with QT-prolonging agents, dopaminergic drugs (like levodopa), or CNS

depressants. Alcohol may intensify sedative effects. Caution with antihypertensive agents due to possible additive hypotension.

Adverse Effects:

Very Common: Extrapyramidal symptoms (tremor, rigidity, dystonia), insomnia, anxiety

Common: Amenorrhea, galactorrhea, gynecomastia, weight gain, somnolence

Rare: Neuroleptic malignant syndrome, prolonged QT interval, allergic skin reactions

Overdose:

Overdose may lead to drowsiness, agitation, coma, or extrapyramidal symptoms. Supportive care and ECG monitoring are essential. No specific antidote is available.

Storage:

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

Manufactured in India for:

Cafeli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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