SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

AMIRED 200 (Amisulpride Tablets BP 200 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated Tablet contain:

Amisulpride BP.....200 mg

Excipients.....Q.S.

3. PHARMACEUTICAL FORM

Tablets.

White coloured round concave shape uncoated dispersible tablets having break line on upper & plain on lower side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is indicated for the treatment of acute and chronic schizophrenic disorders: Positive symptoms with delusions, hallucinations, thought disorders, hostility and suspicious behavior.

Primarily negative symptoms (deficit syndrome) with blunted affect, emotional and social withdrawal.

4.2 Posology and Method of Administration

For acute psychotic episodes the recommended oral dose ranges from 400 to 800 mg/day. In individual cases, the daily dose may be increased up to 1200 mg/day. Doses above 1200 mg/day have not been extensively evaluated for safety and therefore should not be used. No specific titration is required when initiating the treatment with Amisulpride. Doses should be adjusted according to individual response. Maintenance treatment should be established individually with the minimally effective dose. For patients with mixed positive and negative symptoms, doses should be adjusted to obtain optimal control of positive symptoms. It is for oral use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Concomitant prolactin-dependent tumors
Phaeochromocytoma.
Children up to puberty.
Lactation.

4.4 Special Warnings and Precautions for Use

As with other neuroleptics, Neuroleptic Malignant Syndrome, a potentially fatal complication, characterised by hyperthermia, increased muscle rigidity,

autonomic instability, altered consciousness and elevated CPK, may occur. In the event of hyperthermia, particularly with high daily doses, all antipsychotic medicines including Amisulpride should be discontinued.

Amisulpride is eliminated by the renal route. In cases of renal insufficiency, the dose should be decreased and intermittent treatment should be considered.

Amisulpride can lower the seizure threshold. Therefore, patients with a history of seizures should be closely monitored during amisulpride therapy.

In elderly patients, amisulpride therapy, like other neuroleptics, should be used with particular caution because of a possible risk of hypotension or sedation. Reduction in dosage may also be required in case of renal insufficiency.

As with other antidopaminergic agents, caution should be also exercised when prescribing Amisulpride to patients with Parkinson's disease since it may cause worsening of the disease.

Amisulpride should be used only if neuroleptic treatment cannot be avoided.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Contraindicated combinations: Levodopa: reciprocal antagonism of effects between levodopa and neuroleptics. Amisulpride may oppose the effect of dopamine agonists e.g. bromocriptine, ropirinole. Combinations which are not recommended: Amisulpride Mylan may enhance the effects of alcohol. Combinations which must be taken into account:

- CNS depressants including narcotics, anaesthetics, analgesics, sedative H1-antihistamines, barbiturates benzodiazepines and other anxiolytic medicines, clonidine and derivatives.
- Antihypertensive medicines and other hypotensive medications.
- Caution is advised when prescribing amisulpride with medicines known to prolong the QT interval, e.g., class IA antiarrhythmics (e.g., quinidine, disopyramide) and class III antiarrhythmics (e.g., amiodarone, sotalol), some antihistamines, some other antipsychotics and some antimalarials (e.g., mefloquine)

4.6 Fertility, Pregnancy and Lactation

Use of the medicinal product during pregnancy is not recommended unless the benefit outweighs the possible risk.

4.7 Effects on Ability to Drive and Use Machines

Amisulpride can cause somnolence and blurred vision and therefore also reduce the ability to

drive vehicles and operate machines, even when used at recommended doses

4.8 Undesirable Effects

The most commonly observed adverse events are somnolence, dizziness, Nausea, nausea, vertigo, balance disorder, anxiety, fatigue, irritability, aggression, insomnia, depression, and suicidal ideation.

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9 Overdose

Exaggeration of pharmacological effects of the drug has been reported with symptoms such as drowsiness and sedation, coma, hypotension and extrapyramidal symptoms. Fatal outcomes have been reported mainly in combination with other psychotropic agents.

In cases of acute overdose, the possibility of multiple drug intakes should be considered. Since amisulpride is weakly dialysed, hemodialysis is of no use to eliminate the drug.

There is no specific antidote to amisulpride. Appropriate supportive measures should therefore be instituted with close supervision of vital functions including continuous cardiac monitoring due to the risk of prolongation of the QT interval, until complete recovery of the patient.

If severe extrapyramidal symptoms occur, anticholinergic agents should be administered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Psycholeptics; Other antidepressants, ATC code: N05AL05

Mechanism of action Amisulpride binds selectively with a high affinity to human dopaminergic D2/D3 receptor subtypes whereas it is devoid of affinity for D1, D4 and D5 receptor subtypes. Unlike classical and atypical neuroleptics, amisulpride has no affinity for serotonin, α- adrenergic, histamine H1 and cholinergic receptors. In addition, amisulpride does not bind to sigma sites. In animal studies, at high doses, amisulpride blocks dopamine receptors located in the limbic structures in preference to those in the striatum. At low doses it preferentially blocks pre-synaptic D2/D3 receptors, producing dopamine release responsible for its disinhibitory effects.

5.2 Pharmacokinetic Properties

Amisulpride shows two absorption peaks: one which is attained rapidly, one hour post-dose and a second between 3 and 4 hours after administration. Corresponding plasma concentrations are 39 ± 3 and 54 ± 4 ng/ml after a 50 mg dose. The volume of distribution is 5.8 l/kg, plasma protein binding is low (16%) and no drug interactions are suspected. Absolute bioavailability is 48%. Amisulpride is weakly metabolised: two inactive metabolites, accounting for

approximately 4% of the dose, have been identified. There is no accumulation of amisulpride and its pharmacokinetics remain unchanged after the administration of repeated doses. The elimination half-life of amisulpride is approximately 12 hours after an oral dose.

5.3 Preclinical Safety Data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Microcrystalline Cellulose

Starch

Magnesium stearate

Talc

Cross povidone

Colloidal silicon dioxide

Croscarmellose sodium

Kyron T 314 Aspartame

Flavor Strawberry

PVPK 30

Isopropyl Alcohol

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

3 years (36 months)

6.4 Special Precautions for Storage

Do not store above 30°C.

Keep out of reach of children.

6.5 Nature and Contents of Container

30 Tablets in an Alu /Alu Each Blister in a Printed Box with Pack Insert.

6.6 Special Precautions for Disposal and Other Handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Redefine Healthcare Limited

P.O.Box 1907-00606, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER(S)

H2025/CTD11811/25953

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08.07.2025

10. DATE OF REVISION OF THE TEXT

21.08.2026