Horgesic Tablet 35mg/450mg

VIHORxx-0 (SIN)

Composition
Each tablet contains orphenadrine citrate 35mg, paracetamol 450mg

Description
Round, white uncoated tablet, bevel-edged, flat faces, "HD" embossed and scored on the same face. The score line serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses.

Excipients: Colloidal Silicon Dioxide, Partially Pregelatinised Starch, Microcrystalline Cellulose M200D+, Crospovidone, Stearic Acid

Actions
Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

Indications
Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.

Contraindications
Orphenadrine shows some anticholinergic activity and should not be used in patients with glaucoma, prostatic hypertrophy or obstruction at the bladder neck, or myasthenia gravis.

Precautions
- Orphenadrine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.
- Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.
- Safety of continuous long-term therapy with orphenadrine has not been established. Therefore, if orphenadrine is prescribed for prolonged use, periodic monitoring of blood, urine and liver function is recommended.

Serious skin reactions
Rarely, **paracetamol** may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal.
Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Use in Pregnancy
Safe use in pregnancy has not been established, therefore the drug should not be used in pregnant women or those likely to become pregnant unless the expected benefits outweigh the potential risks.

Use in lactation
Horgesic should not be taken during lactation as orphenadrine and paracetamol are excreted into breast milk.

Elderly
The elderly should be advised to take a reduced dosage as they may be more susceptible to anticholinergic side effects at regular doses.

Paediatric use
Horgesic is not recommended for children under 12 years of age.

Drug Interactions
The effects of antimuscarinic agents such as orphenadrine maybe enhanced by other drugs with antimuscarinic properties such as amantadine, some antihistamines, butyrophenones and phenothiazines, and tricyclic antidepressants. The reduction in gastric motility caused by antimuscarinic agents may affect the absorption of other drugs

Adverse Reactions
Side effects rarely occur at the recommended dosage. Those encountered are associated with anticholinergic activity and may include nausea, dry mouth, blurring of vision. Rarely, rash or drowsiness may occur. These symptoms disappear rapidly with a reduction in dosage or cessation of medication. No toxic effects have been observed.

Overdosage
Symptoms:
Symptoms of orphenadrine overdosage are excitement, confusion, delirium leading to coma. Convulsions and tachycardia with dilated pupils and urinary retention may occur.
Paracetamol overdosage may cause acute liver damage, but symptoms may not appear for up to several days after ingestion.

Treatment:
Gastric lavage should be carried out immediately regardless of the estimated ingested dose. Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth. Adequate hydration of the patient is important. It is recommended that the patient be referred to a hospital where early and regular monitoring of plasma paracetamol levels can be carried out. If instituted sufficiently early, treatment with N-acetylcysteine, L-methionine or L-cysteamine will minimise liver damage.

Dosage and Administration
Adult : Oral, 1 to 2 tablets three to four times daily up to a maximum of 8 tablets per day.
Children : Not recommended in children.

Note: The information given here is limited. For further information consult your doctor or pharmacist.

Storage :
Store below 30˚C. Protect from light and moisture.

Presentation/Packing : Blisters of 10 x 10's.
Product Owner : **HOVID Bhd.**,
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.
Manufactured by : **HOVID Bhd.**,
Lot 56442, 7 $^{1}/_{2}$ Miles, Jalan Ipoh /
Chemor, 31200 Chemor, Perak, Malaysia.

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