hovid Paracetamol + Orphenadrine Citrate
Tablet 450mg / 35mg

VIPARfa-PC (FEO)

DESCRIPTION
Round, 12 mm diameter, white to off-white uncoated tablet, bevel edged, flat faces, "HD" embossed and scored on the same face.

COMPOSITION
Each tablet contains:

Paracetamol	450 mg
Orphenadrine citrate	35 mg

PHARMACODYNAMICS
Paracetamol
Paracetamol is an analgesic and antipyretic. It may act by inhibiting prostaglandin synthesis in the central nervous system (CNS) and through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition to the synthesis of prostaglandins or to inhibition of the synthesis or actions or other substances, which sensitize pain receptors to mechanical or chemical stimulation.

Orphenadrine
Orphenadrine is a skeletal muscle relaxant. The precise mechanism of action of orphenadrine is unknown. It may act in the central nervous system (CNS) to depress polysynaptic reflexes. Its skeletal muscle relaxant properties may be related to its CNS depressant (sedative) or to its analgesic effects. It also has weak antihistaminic and local anesthetic properties.

PHARMACOKINETICS
Paracetamol is absorbed rapidly and almost completely following administration; may be decreased if taken following a high-carbohydrate meal.

Orphenadrine is readily absorbed from the gastro-intestinal tract. Being metabolized in liver the liver and most of the dose is excreted in the urine along with a small proportion of unchanged drug.

INDICATION
For relief of 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
Glaucoma, prostatic hypertrophy or obstruction at the bladder neck, myasthenia gravis, oesophageal spasm and pyloric or duodenal obstruction.
Hypersensitivity to paracetamol or orphenadrine citrate.

WARNING AND PRECAUTIONS
This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.
- Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency or cardiac arrhythmias.
- Paracetamol should be used with caution in patients with hepatic or renal dysfunction.
- Concomitant treatment with other medicines that contain orphenadrine or paracetamol is not recommended.
- 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.

Allergy alert
Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop to use and seek medical assistance right away.

Effects on ability to drive and use machine
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.

PREGNANCY AND LACTATION
This product is not recommended for use during pregnancy.
This product should not be taken during lactation as orphenadrine and paracetamol are excreted into breast milk.

DRUG INTERACTIONS
- Interactions have been reported between orphenadrine and phenothiazines and other drugs with anti-muscarinic properties. Concomitant use with alcohol or other CNS depressants should be avoided.
- Anticoagulant dosage may require reduction if paracetamol medication is prolonged.
- Paracetamol absorption is increased by medicines that increase gastric emptying, e.g. metoclopramide, and decreased by medicines that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties and narcotic analgesics.
- Paracetamol may increase chloramphenicol concentrations. The likelihood of paracetamol toxicity may be increased by the concomitant use of enzyme inducing agents such as alcohol or anticonvulsant medicines.

MAIN SIDE/ADVERSE EFFECTS
Adverse effects are mainly due to the anti-cholinergic action of orphenadrine and are usually associated with higher doses.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome / Toxic Epidermal Necrolysis have been reported.

Orphenadrine citrate
More common reactions
- The known adverse effects include; dryness of the mouth, tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilation of the pupils, increased ocular tension, weakness, nausea, headache, dizziness, constipation and drowsiness. These effects can usually be eliminated by reducing the dose.

Less common reactions
- Sedation, skin rashes and other allergic reactions are very uncommon adverse effects.
- Infrequently an elderly patient may experience some degree of mental confusion. Very rare cases of aplastic anaemia associated with the use of orphenadrine have been reported.

Paracetamol
- Reports of adverse reactions are rare. Although the following reactions have been reported, a causal relationship to the administration of paracetamol has been neither confirmed nor refuted; dyspepsia, nausea, allergic and haematological reactions.

OVERDOSE AND TREATMENT
Orphenadrine overdosage
Known symptoms of overdose with orphenadrine include tachycardia, excitement, confusion and delirium leading to coma. Convulsions, dilated pupils and urinary retention may occur.

Paracetamol overdosage
Toxic symptoms following an overdose with paracetamol include vomiting, abdominal pain, hypotension, sweating, central stimulation with exhilaration and convulsions in children, drowsiness, respiratory depression, cyanosis and coma.

Treatment
Prompt administration of activated charcoal 50 g in 150 mL of water and 150 mL sorbitol 50% solution by mouth may reduce absorption.

It is recommended that intravenous fluids such as normal saline be given concurrently.

Gastric lavage is indicated if the patient is unwilling or unable to drink an activated charcoal/sorbitol mixture.

Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth.

Adequate hydration of the patient is important.

DOSAGE AND ADMINISTRATION
Oral, 2 tablets three times daily.

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

Storage:
Store below 25˚C.
Protect from light and moisture.

Presentation/Packing:
Tablet x 500's, 1000's, Polyvinyl Chloride (PVC) Blisters of 10 x 10's.

Product Registration Holder: HOVID Pharmacy Sdn. Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Manufactured by: HOVID Bhd.
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31200 Chemor, Perak, Malaysia.

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