SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name
Anorol Tablet

1.2 Strength
Paracetamol 450.0 mg and Orphenadrine Citrate 35.0 mg

1.3 Pharmaceutical Dosage Form
Tablet

2-Quality and Quantitative Composition :

No	Name of Ingredient	mg/tablet
1	Paracetamol	450.00
2	Orphenadrine Citrate	35.00

For excipients, see 6.1

3-Pharmaceutical Form:
Round, white uncoated tablet, bevel-edged, flat faces, "HD" embossed and scored on the same face.

4-Clinical Particulars

4.1 Therapeutic indications
For the relief of mild to moderate pain of acute musculoskeletal disorders and tension headache

4.2 Posology and method of administration
For oral use

Adult:
Oral, 1 to 2 tablet 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

4.3 Contraindications
This medication should not be used in the following conditions:
- Patients with acute porphyria-aspirin-sensitive asthmatics.

- Patients with conditions in which anticholinergic effects are undesirable.

4.4 Special warning and precautions for use

This medication should be given with care to patients with hepatic or renal function impairment, glaucoma, cardiac arrhythmias, coronary insufficiency or peptic ulceration.

- Chronic use should be avoided, unless otherwise directed by physician.
- Safety for use during pregnancy and lactation has not been established.
- The usual precautions and contraindications associated with antimuscarinics should be observed with orphenadrine.
- This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time

4.5 Interaction with other medicinal products and other forms of Interactions

This medication should not be used with the following drugs:
Hepatic enzyme-inducing agents such as barbiturates or other anticonvulsants, general anaesthetics, CNS depressants, monoamine oxidase (MAO) inhibitors, tricyclic antidepressants.

4.6 Pregnancy and lactation

None known

4.7 Effects on ability to drive and use machine

None known

4.8 Undesirable effects

- Side-effects of this medication include dry mouth, mydriasis, cyclopegia, urinary urgency, constipation and mental confusion.
- Other side-effects which occur rarely include blood dyscrasias, hepatitis, hypersensitivity reactions such as skin rash, hives or itching, increased intraocular pressure, tachycardia, CNS stimulation usually manifested by restlessness, insomnia and hallucinations, transient episodes of lightheadedness, dizziness or syncope.

4.9 Overdose and special antidotes.

Clinical features: Nausea, vomiting or epigastric discomfort for the first two days. Hepatic and renal failure may occur after 3-5 days. Other symptoms include metabolic acidosis in severe poisoning, hypoglycaemia, hypotension, sinus tachycardia, cardiac arrhythmias, coma, dry mouth, disturbance of visual accommodation and micturition, tachycardia, hyperthermia, dizziness, confusion, hallucinations, excitement, ataxia and convulsions.

Treatment include emesis or gastric lavage if appropriate. Activated charcoal may interfere with absorption of the antidote, N-acetylcysteine. If the 4 hour plasma paracetamol level exceeds 150 ug/ml, administer N-acetylcysteine orally, 140 mg of 20% solution per kg as a loading dose, followed by 70 mg/kg every 4 hours for 3 days (best given within 10 hours after ingestion. Others include symptomatic and supportive treatment.

5-Pharmacological Properties:

5.1 Pharmacodynamic Properties

Paracetamol has analgesic and antipyretic actions. It may act by inhibiting prostaglandin synthesis in the central nervous system and through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of the synthesis or actions of other substances which sensitize pain receptors to mechanical or chemical stimulation. Its antipyretic property may be due to its action on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss.

Orphenadrine may act on the central nervous system to depress polysynaptic reflexes. Its skeletal muscle relaxant properties may be related to its CNS depressant (sedative) or to its analgesic effects.

5.2 Pharmacokinetic Properties

This medication is well absorbed after oral administration, metabolized in the liver and excreted in the urine.

5.3 Preclinical safety Data

NOT AVAILABLE

6-Pharmaceutical Particulars:

6.1 List of excipients

Lactose Monohydrate
Polyvinylpyrrolidone
Colloidal Silicon Dioxide
Citric Acid
Magnesium Stearate
Hydroxypropyl Methylcellulose
Sodium Bicarbonate
Sodium Starch Glycolate
Purified Water

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture.

6.4 Special precautions for storage

Store below 25°C. Protect from light and moisture.

6.5 Nature and contents of container

Immediate Container Closure System / Primary Packaging

Primary Packaging

Blister pack

Type

Push-through blister pack; the package consists of a transparent thermoformable plastic material and a heat-sealed, lacquered backing material.

Rigid PVC film

Description	:	Rigid PVC film
Appearance	:	Glass clear transparent film

Aluminium blister foil

Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface/Aluminium foil with high slip primer on matt surface and heat seal on bright surface
Appearance	:	Bright surface/Matt surface each side

Outer Container / Secondary Packaging

Outer Container/Packaging
Type: Unit box, Package Insert & Plain Carton Anorol Tablet

7-Marketing Authorization Holder:

Name	:	HOVID Bhd.
Address	:	121, Jalan Tunku Abdul Rahman, (Jalan Kuala Kangsar) 30010 Ipoh, Perak, Malaysia

8-Manufacturer Name:

Name	:	HOVID Bhd.
Address	:	Lot 56442, 7 ½ Miles, Jalan Ipoh / Chemor, 31200 Chemor, Perak., Malaysia.

9-Date of first authorization/renewal of the authorization:

10-Date of revision of the text:

June 2023