Norgesic® Tablet

PRODUCT DESCRIPTION
White, scored, biconvex tablet marked: Upper Face: N/C, Lower Face has no markings.

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

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

PHARMACOKINETICS
Orphenadrine is readily absorbed from the gastrointestinal tract and is almost completely metabolised to at least eight metabolites. Orphenadrine and its metabolites are excreted from the body in the urine, with a half life of 14 hours.
Paracetamol is also readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues.
It has a half life of between 1 to 3 hours.

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.

DOSAGE AND ADMINISTRATION
2 tablets three times daily.

ROUTE OF ADMINISTRATION
Oral

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.

WARNINGS AND 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.

Warning

This preparation contains PARACETAMOL.
Do not take any other paracetamol containing medicines at the same time.

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 use and seek medical assistance right away.

PREGNANCY AND LACTATION

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
It is unknown whether orphenadrine is excreted during lactation.
However it is established that paracetamol is excreted into the breast milk, one to two hours after oral administration.

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SPACE FOR PHARMACODE
9 mm × 25 mm (2.5mm)
187 mm
153 mm

DRUG INTERACTION
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 EFFECTS
Adverse effects are mainly due to the anti-cholinergic action of orphenadrine and are usually associated with higher doses.

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, hallucinations, 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.

The following reactions have been reported: dyspepsia, sweating, erythema, urticaria, anaphylactic shock, angioneurotic oedema, difficulty breathing, drop in blood pressure, nausea, allergic reactions such as skin rashes, hypersensitivity reactions and haematological reactions, including thrombocytopenia, leukopenia, neutropenia, agranulocytosis and pancytopenia.
Toxic Epidermal Necrolysis (TEN), Stevens-Johnson Syndrome (SJS), acute generalised exanthematous pustulosis, fixed drug eruption (see Section Warnings and Precautions) and cytolytic hepatitis, which may lead to acute hepatic failure, have also been reported.

Bronchospasm may be triggered in patients having a tendency of analgesic asthma.

Haemolytic anaemia, particularly in patients with underlying glucose 6-phosphate-dehydrogenase deficiency has been reported. Kounis syndrome has been reported, as has high anion gap metabolic acidosis due to pyroglutamic acidosis in patients with pre-disposing factors for glutathione depletion.

OVERDOSE
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 apper 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.

STORAGE
Store below 30˚C.

PACKAGING INFORMATION
Available in packing of 50x12's and 1x12's.

MANUFACTURED BY
Adcock Ingram Ltd-A Medreich Group Company
No. 49 C&D, Bommasandra Industrial Area,
Anekal Taluk, Bangalore 560099, India.

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inova pharmaceuticals

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NORGESIC TABLET 600 SEA- PIL
DIMENSION.: 153x187 mm

RE-TYPESET ARTWORK. Due to the nature of the files received, this artwork has been re-typeset.

GROUP 24|7 WORLDWIDE™ | inova pharmaceuticals | **ARTWORK**

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28.11.25 - V0 - Artwork build - Pornpawee
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Colour 100% — Black — Guide

PLEASE NOTE
This HI RES PDF is not to be used as Final Artwork

Supplier information may be present on the packaging

EMO/Printing Vendor:
Please share the Artwork PDF to Printer for checks on:
- Colours - No. of colours, Sequence, CMYK/PMS
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Moving forward when possible any additonal information and technical check required by EMO on the Artwork BEFORE APPROVING.

Norgesic® Tablet — 3.67 mm 14.00 pt

PRODUCT DESCRIPTION — 1.88 mm 7.00 pt
White, scored, biconvex tablet marked: Upper Face: N/C, Lower Face has no markings. — 1.82 mm 7.00 pt

A11267 — 1.82 mm 7.00 pt