Provas®-N / Provas®-N Forte Tablets

(Paracetamol + Orphenadrine Citrate) (Paracetamol + Orphenadrine Citrate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Provas®-N Tablets
Each tablet contains:
Paracetamol BP.....450mg
Orphenadrine Citrate BP.....35mg

Provas®-N Forte Tablets
Each tablet contains:
Paracetamol BP.....650mg
Orphenadrine Citrate BP.....50mg

PHARMACEUTICAL FORM

Tablets

CLINICAL PARTICULARS

THERAPEUTIC 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.

POSOLOGY AND METHOD OF ADMINISTRATION:

Provas®-N: Two tablets three times daily or as directed by the physician.
Provas®-N Forte: One tablet twice daily or as directed by the physician.

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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Identified precautions
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.

Use in the 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
Not recommended for children under 12 years of age.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
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.

FERTILITY, PREGNANCY AND LACTATION:
Fertility
No data available

Pregnancy:Pregnancy Category B2:
Not recommended for use during pregnancy.

Breast-feeding
Should not be taken during lactation as orphenadrine and paracetamol are excreted into breast milk.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
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.

UNDESIRABLE 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, 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:
No specific information is available on over dosage.
Overdose of paracetamol can result in severe liver damage and sometimes acute renal tubular necrosis.

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

Paracetamol over dosage
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.
In adults, hepatotoxicity may occur after ingestion of a single dose of paracetamol 10 to 15g; a dose of 25g or more is potentially fatal. Symptoms during the first two days of acute poisoning by paracetamol do not reflect the potential seriousness of the intoxication. Major manifestations of liver failure such as jaundice, hypoglycaemia and metabolic acidosis may take at least three days to develop.

Treatment
Prompt treatment is essential even when there are no obvious symptoms. In cases of overdosage, methods of reducing absorption of ingested medicine are important. Prompt administration of activated charcoal 50g in 150mL of water and 150mL 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.

210 mm

120 mm

If the history suggests that paracetamol 150mg/kg body weight or 15g total or more has been ingested, administer the following antidote:

Intravenous acetylcysteine 20%:
Administer acetylcysteine immediately without waiting for positive urine test or plasma level results if 8 hours or less since overdose ingestion. Initial dose 150mg/kg over 15 minutes, followed by continuous infusion of 50mg/kg in glucose 5% 500mL over four hours and 100mg/kg in glucose 5% 1 L over 16 hours. If more than eight hours have elapsed since the overdose was taken, the antidote may be less effective.

Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth. Adequate hydration of the patient is important.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:
ATC code: M03BC51

MECHANISM OF ACTION:
Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

PHARMACOKINETIC PROPERTIES:
No data available.

STABILITY

See expiry on the pack.

AVAILABILITY

Provas®-N tablets in a pack of 96's
Provas®-N Forte tablets in a pack of 20's

INSTRUCTIONS

Dosage as advised by physician.
To be sold on the prescription of registered medical practitioner.
Keep out of reach of children.
Avoid exposure to heat, light and humidity.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.
Store in the original package in order to protect from moisture.

Please read the contents carefully before use.
This package insert is regularly reviewed and updated.

پرووواس-این/ پرووواس-این فورٹ ٹیبلٹ

(پیراسیٹامول+ اورفینادرین سائٹریٹ) (پیراسیٹامول+ اورفینادرین سائٹریٹ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔
دوا کو نمی سے محفوظ رکھنے کے لیے اسکی اصل پیکنگ میں رکھیں۔

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210 mm

120 mm