

DYCOSIC TABLET

Orphenadrine citrate (35 mg) and Paracetamol (450 mg)

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1. What *DYCOSIC* is used for

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.

2. How *DYCOSIC* works

Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic. Orphenadrine, which is a congener of diphenhydramine without sharing its soporific effect, is an antimuscarinic agent. It also has weak antihistaminic and local anaesthetic properties. Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties.

3. Before you use *DYCOSIC*

- When you must not use it

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

Pregnancy and lactation

Use in pregnancy

DYCOSIC is not recommended for use during pregnancy.

Use in lactation

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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.

4. How to use *DYCOSIC*

- How much to use

2 tablets three times daily.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *DYCOSIC* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms and Signs Orphenadrine overdose: Known symptoms of overdose with orphenadrine include tachycardia, excitement, confusion and delirium leading to coma.

Convulsions, dilated pupils and urinary retention may occur.

Paracetamol overdose: 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 overdose, methods of reducing absorption of ingested medicine are important.

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.

If the history suggests that paracetamol 150mg/kg body weight or 15 g 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 150 mg/kg over 15 minutes, followed by continuous infusion of 50 mg/kg in glucose 5% 500 mL over four hours and 100 mg/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

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effective.

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

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DYCOSIC.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give DYCOSIC to anyone else, even if they have the same symptoms or condition as you.

DYCOSIC contains PARACETAMOL.

Do not take any other paracetamol containing medicines at the same time.

- Things to be careful of

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.

Paediatric use

DYCOSIC is not recommended for children under 12 years of age.

Use in the elderly

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

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.

Effect on ability to drive or operate machinery

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.

6. Side effects

Like all medicines, DYCOSIC can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Orphenadrine citrate

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

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

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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

7. Storage and Disposal of DYCOSIC

- Storage

Keep out of the reach and sight of children.

Store in dry place below 30°C.

Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

Tablets (white, oblong, convex and uncoated)

- Ingredients

- Active ingredient(s)
Orphenadrine citrate 35 mg
Paracetamol 450 mg.

- Inactive ingredients

Corn starch, lactose powder, sodium starch glycolate, microcrystalline cellulose, PVP K90, magnesium stearate & aerosil.

MAL number(s):

MAL18056180AZ

9. Manufacturer & Product

Registration Holder

DYNAPHARM (M) SDN. BHD.

2497, Mukim 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, MALAYSIA

10. Date of revision

15/05/2023

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