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 110(L) x 260(H)mm  
 Draft : 03 Oct 2019

# ORPHENADOL<sup>®</sup> TABLET

## Ingredient(s):

Each tablet contains:

Orphenadrine Citrate ..... 50mg  
 Paracetamol ..... 325mg

## Pharmacodynamics:

1. Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties.
2. Orphenadrine Citrate, which is a congener of Diphenhydramine without sharing its soporific effect, is an antimuscarinic agent. It also has weak antihistaminic and local anaesthetic properties which may contribute to its skeletal muscle relaxant properties.

## Pharmacokinetics:

1. Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine. Less than 5% is excreted as unchanged Paracetamol. Elimination half-life varies from about 1 to 4 hours. Orphenadrine Citrate is readily absorbed from the gastrointestinal tract. It is rapidly distributed in tissues and most of the dose is metabolised and excreted in the urine along with a small proportion of unchanged drug. A half-life of 14 hours has been reported.

## Indication(s):

Indicated as an adjunct to other measures, such as rest and physical therapy, for relief of pain and muscle spasm associated with acute painful musculoskeletal conditions.

## Route of Administration: Oral

## Dosage and Administration(s):

Usual adult dose is 1 tablet twice to four times daily. The dosage should be adjusted according to symptoms and age.

To be dispensed on physician's prescription.

## Contraindication(s):

Hypersensitivity to paracetamol, Orphenadrine Citrate and in patients with prostatic enlargement, with paralytic ileus or pyloric stenosis, G-6PD deficiency, tardive dyskinesia, porphyria, urinary retention, glaucoma.

## Interactions with Other-medicaments:

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.

Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.

Warfarin: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Chloramphenicol: Increased plasma concentration of chloramphenicol.

## Precaution(s)/ Warning(s):

Orphenadol should be given with care to patients with impaired renal or liver function, taking other drugs that affect the liver and myasthenia gravis. 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

## Side Effects(s):

Side effects rarely occur at the recommended dosage. Those encountered are

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associated with anticholinergic activity and may include nausea, dry mouth, blurring of vision. Rarely, rash or drowsiness may occur. These symptoms disappear rapidly with a reduction in dosage or cessation of medication. No toxic effects have been observed. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

**Symptoms and Treatment of Overdose(s):**

**Overdosage Symptoms:**

Symptoms of orphenadrine overdose are excitement, confusion, delirium leading to coma. Convulsions and tachycardia with dilated pupils and urinary retention may occur. Paracetamol overdose may cause acute liver damage, but symptoms may not appear 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.

**Effects on Ability to Drive and Use Machine:**

Orphenadrine may cause blurred vision or slight euphoria. If patients experience these side effects, driving or operating machinery is not recommended.



**Storage Condition(s):**

Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

**Shelf Life(s):**

3 years from the date of manufacture.

**Product Description:**

A white round tablet, one side impressed with a score "  " and the other side with a mark "  "

**Packing(s):**

Blister packing of 10's x 10 and 10's x 100.  
 Plastic bottle of 1500's

L  
 260mm



Manufacturer and Product Registration Holder:  
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 Ordering Line: 1 800 88 3027  
 Product Info: 1 800 88 3679

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W  
 110mm

260 x 110