Item Code	: 204078 - 06 draft 08 July 2022

ORPHENADOL® TABLET

Ingredient(s):
Each tablet contains:
Orphenadrine Citrate 50mg
Paracetamol 325mg

Action(s):
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 with actions and uses similar to those of Benzhexol. It also has weak antihistaminic and analgesic activity which may contribute to its skeletal muscle relaxant properties.
3. 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.

Dosage and Administration:
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, anemia, cardiac, pulmonary, renal or hepatic diseases.

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.
Serious skin reactions
Rarely, paracetamol may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Side Effect(s) / Adverse Reaction(s):
Side effects of Paracetamol are usually mild though haematological reactions have been reported. Skin rashes are other allergic reactions occur occasionally. Side effects of Orphenadrine with low incidence include fainting (CNS effects), unusually fast or pounding heartbeat, abdominal or stomach cramps or pain, nausea, vomiting, blurred vision, confusion, constipation and dizziness or lightheadedness.

Drug Interaction(s):
This preparation contains Paracetamol. Do not take any other Paracetamol-containing drugs at the same time. Do not take NSAIDs together with this preparation for more than a few days. Orphenadrine may add to the effects of alcohol and other CNS depressants. Some examples of CNS depressants are antihistamines, or medicine for hay fever, other allergies, or colds, sedatives, tranquilizers, or sleeping medicines; prescription pain medicine or narcotics, barbiturates, medicine for seizures, other muscle relaxants, or anesthetics, including some dental anesthetics.
Although studies have not been done in pregnant women, Paracetamol and Orphenadrine have not been reported to cause birth defects or other human problems.

Symptoms and Treatment for Overdosage and Antidote(s):
When overdosage, patients should undergo gastric lavage, specific therapy with an antidote such as Acetylcysteine or Methionine. Administration of intravenous fluids, and circulatory support may be required. Hemodialysis or peritoneal dialysis may be of some benefit if the serum concentration exceeds 4µg per ml.

Shelf-Life:
3 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

L
260mm
±
2mm

W
110mm ± 2mm

Item Code	: 204078 - 06 draft 08 July 2022

Packing:
Plastic bottle of 1000's and 1500's.
Blister packing of 10's x 10 and 10's x 100.
(Not all pack sizes may be available)

L
260mm
±
2mm

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan, Malaysia.

Y. S. P.®

Product Registrant and Importer:
YUNG SHIN PHARMACEUTICAL (S) PTE. LTD.
10, Ubi Crescent, # 06-57/58 Ubi Techpark,
Singapore 408564

xxxxxx printing code xxxxxx

Date of revision: 08 July 2022

W
110mm ± 2mm