28x16 cm

# Trimed Flu film coated tablet

#### **COMPANY NAME :**

Minapharm Company For Pharmaceuticals & Chemical Industries

#### TRADE NAME :

Trimed flu film coated tablet

#### **GENERIC NAME:**

Paracetamol & Pseudoephedrine sulphate and Loratadine

#### **COMPOSITION :**

Each film coated tablet contains: Paracetamol 500 mg. Pseudoephedrine sulphate 120 mg, Loratadine 5 ma Inactive ingredients : Corn starch, Hydroxypropyl methyl cellulose (2910), Dibasic calcium phosphate dehydrate, Stearic acid, Magnesium stearate, Polyethylene glycol 3350, Dye Opaspray white, Polyethlene glycol 400.

#### **PHARMACEUTICAL FORM:**

Film coated Tablet

# **PHARMACOLOGICAL ACTIONS :**

Loratadine is a long acting antihistamine

Pseudoephedrine sulphate, is an orally active sympathomimetic amine which exerts a decongestant action on the nasal mucosa.

Paracetamol is an effective and fast acting analgesic and antipyretic

which acts centrally to relieve mild to moderate pain.

#### **PHARMACOKINETICS:** Paracetamol

Absorption: rapidly absorbed from the gastrointestinal tract and is distributed throughtout most body tissues. The plasma half-life is 1.25 to 3 hours, but may be increased by liver damage and following overdosage. Elimination: is principally by liver metabolism (conjugation) and subsequent renal excretion of metabolites. Loratadine + Pseudoephedrine

# sulphate :

Absorption: Co- administration of loratadine and pseudoephedrine sulphate does not significantly affect the bioavailability of either component. Distribution: No plasma protein binding data in humans are available. **Metabolism:** 70 % of the administered dose was recovered in the urine and 10 % in the feces. Elimination: The mean elimination

half-life of loratadine is 7.9 hours and the mean elimination half-life of pseudoephedrine is 6 hours.

## **INDICATIONS:**

Indicated for the relief of symptoms of seasonal allergic rhinitis associated with moderate to severe pain. It is also indicated in sinusitis for the relief of sinus pain, congestion & fever.

#### **DOSAGE & ADMINISTRATION :**

One tablet twice a day (every 12

hours).

# CONTRA-INDICATIONS:

It is contraindicated in patients who are hypersensitive to any of its ingredients. This product, due to its pseudoephedrine component, is contraindicated in patients with narrow angle glaucoma or urinary retention, and in patients receiving monoamine oxidase (MAO) inhibitor therapy or within fourteen (14) days of stopping such treatment. It is also contraindicated in patients with severe hypertension, severe coronary artery disease, and in those who have shown hypersensitivity or idiosyncrasy to its components, to adrenergic agents, or to others drugs of similar chemical structures. Manifestations of patient idiosyncrasy to adrenergic include: insomnia, dizziness, weakness, tremor, or arrhythmias.

#### SIDE EFFECTS:

Headaches, insomnia, dry mouth, somnolence, nervousness, dizziness, fatigue, dyspepsia, nausea, pharyngitis, anorexia & thirst.

## DRUG INTERACTIONS:

No specific interactions studies have been conducted with loratadine, pseudoephedrine & paracetamol tablets. However, loratadine (10 mg once daily ) has been safely coadministered with therapeutic doses of erythromycin, cimetidine, Ketoconazole in controlled clinical

pharmacology studies.

Loratadine, pseudoephedrine & paracetamol tablets (pseudoephedrine component) are contraindicated in patients taking monoamine oxidase (MAO) inhibitors, and for 2 weeks after stopping use of an MOA inhibitor. The antihypertensive effects of beta-adrenergic blocking agents, methyldopa, mecamylamine, reserpine and veratum alkaloids may be reduced by sympathomimetics. Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis. Patients receiving CNS depressants such as anesthetics, hypnotics, sedatives, tranguilizers and alcohol concomitantly with Loratadine, paracetamol & pseudoephedrine tablets may exhibit an additive CNS depression.

Barbiturates and prolonged alcohol ingestion may increase the metabolism of paracetamol to metabolites toxic to the liver.

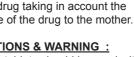
## **PREGNANCY & LACTATION:**

There are no adequate and well controlled studies in pregnancy. A decision should be made whether to discontinue nursing or to discontinue using the drug taking in account the importance of the drug to the mother.

## PRECAUTIONS & WARNING :

Trimed Flu tablets should be used with caution in patients with hypertension, diabetes mellitus, ischemic heart MINAPHARM







pressure, hyperthyroidism, renal impairment or prostatic hypertrophy. Central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension may be produced by sympathomimetic amines.

disease, increased intraocular

# **INSTRUCTIONS FOR PATIENTS :**

Trimed Flu tablets contain paracetamol so caution should be taken when the drug is taken with other medications containing the same active ingredient. Trimed Flu tablets should be used with caution in patients with hypertension due to its pseudoephedrine sulphate content.

# STORAGE :

Trimed Flu film coated tablets should be stored at temperature not exceeding 30°C in dry place.

## PACKAGE :

Carton box contains 2 strips + inner leaflet. Each strip contains 10 tablets.

Manufactured by Minapharm -Egypt