

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 mg

Inactive ingredients : Corn starch,
Hydroxypropyl methyl cellulose
(2910), Dibasic calcium phosphate
dehydrate, Stearic acid, Magnesium
stearate, Polyethylene glycol 3350,
Dye Opaspray white, Polyethylene
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 throughout 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,
somnia, 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, mecamlamine, 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, tranquilizers 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

disease, increased intraocular
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.

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**



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