TRIDIN-P TABLETS AND SYRUP

NAME AND STRENGTH OF ACTIVE INGREDIENT(S)

(i) **Tridin-P Tablet:**

Each tablet contains: Pseudoephedrine Hydrochloride …… 60mg
Triprolidine Hydrochloride …… 2.5mg

(ii) **Tridin-P Syrup:**

Each 5ml syrup contains: Pseudoephedrine Hydrochloride …… 30mg
Triprolidine Hydrochloride …… 1.25mg

PRODUCT DESCRIPTION:

(i) Tridin-P Tablet: A white, round, scored of diameter 8.5mm flat tablet with 'MPI' marking.
(ii) Tridin-P Syrup: A light yellow liquid with lemon flavour and sweet taste.

PHARMACODYNAMICS:

Triprolidine is a long acting antihistamine with anticholinergic activity. It is a potent competitive histamine H_1- receptor antagonist of alkyl (propyl)-amine class which competes with histamine for H_1- receptor sites on effector cells and provides symptomatic relief in allergic conditions triggered by histamine release. Pseudoephedrine is a stereoisomer of ephedrine which is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. Pseudoephedrine acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. It shrinks swollen nasal mucuos membranes, reduces tissue hyperemia, edema and nasal congestion, and increases nasal airway patency.

PHARMACOKINETICS:

Triprolidine is readily absorbed from the gastrointestinal tract after oral administration. It is mostly metabolised in the liver and excreted usually mainly as metabolites in the urine. It has a rapid onset and long duration of action. The maximum effect occurs in about $3^1/_2$ hours; the duration of effect is about 12 hours. Pseudoephedrine is readily and completely absorbed from the gastrointestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine. It has a half-life of several hours; elimination is enhanced and half-life accordingly shorter in acidic urine.

INDICATION:

TRIDIN-P which is the combination of triprolidine hydrochloride (a potent antihistamine) and pseudoephedrine hydrochloride (a potent decongestant) is used as a nasopharyngeal and otic decongestant as well as for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis.

RECOMMENDED DOSAGE:

To be taken orally. May be taken with food, or milk to lessen gastric irritation.
To minimize the possibility of insomnia from pseudoephedrine, the last dose for each day should be administered a few hours before bedtime.

Dosage for adults and children over 12 years:
1 tablet or 10ml syrup three or four times a day as needed; not to exceed 4 tablets or 40ml syrup per day.

Children under 12 years:

6-12 years : ½ tablet or 5ml syrup three or four times a day as needed; not to exceed 2 tablets or 20ml syrup per day.
4-6 years : 3.75ml syrup three or four times a day as needed; not to exceed 15ml per day.
2-4 years : 2.5ml syrup three or four times a day as needed; not to exceed 10ml per day.

Not to be used in children less than 2 years of age.
To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

ROUTE OF ADMINISTRATION:

Oral

CONTRAINDICATIONS:

1. Known hypersensitivity to either triprolidine or pseudoephedrine or with known hypersensitivity to other antihistamines or sympathomimetics.
2. During pregnancy and lactation.
3. Use in newborn or premature infants.
4. Concurrent use of monoamine oxidase (MAO) inhibitors; may potentiate the pressor effect of pseudoephedrine, possibly resulting in hypertensive crisis; the preparation should not be administered during or within 14 days following administration of MAO inhibitors.

5. Patients with hypertension, hyperthyroidism, ischemic heart disease, or cerebrovascular disease.

WARNINGS AND PRECAUTIONS:

Not to be used in children less than 2 years of age.

To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

As TRIDIN-P consists of an anihistamine and a sympathomimetic, it should be used with caution in patients with closed-angle glaucoma, prostatic hypertrophy, diabetes, hyperthyroidism, cardiac diseases, hypertension, epilepsy, stenosing peptic ulcer, intestinal obstruction.

Triprolidine may cause some people to become drowsy, dizzy or less alert than they are normally. Patient undergoing treatment should avoid to take charge of vehicles, other means of transport or machinery where loss of attention may lead to accidents. Patients should abstain from alcohol.

INTERACTIONS WITH OTHER MEDICAMENTS:

1. Alcohol or other CNS depressants or tricyclic antidepressants : concurrent use may potentiate the sedative effects of either these medications or antihistamine.
2. Beta-adrenergic blocking agents: concurrent use may increase the pressor effect of pseudoephedrine.
3. Digitalis glycosides : concurrent use may increase the possibility of cardiac arhythmias.
4. Guanethidine, Mecamylamine, Methyldopa, Reserpine or Veratrum alkaloids: hypotensive effects may be decreased when used concurrently due to the presence of pseudoephedrine.
5. Monoamine oxidase (MAO) Inhibitors: concurrent use may potentiate the pressor effects of pseudoephedrine, possibly resulting in a hypertensive crisis; the preparation should not be administered during or within 14 days following administration of MAO inhibitors.
6. Other Sympathomimetics: concurrent use may increase the effects of either these medications or pseudoephedrine and the potential for side effects.

PREGNANCY AND LACTATION:

Pregnancy: Should be used during pregnancy only when clearly needed.

Lactation : Antihistamines have the potential for serious adverse reactions in nursing infants.

Pregnant or nursing women should consult a doctor before use.

SIDE EFFECTS:

TRIDIN-P might cause drowsiness and dryness of the mouth; insomnia may occur. Difficult urination, headache, loss of appetite, nausea or vomiting, restless, unusual weakness, unusual fast or pounding heartbeat, stomach upset and skin rash might occur.

With high doses : hallucinations, palpitations, hypertension, tachycardia and convulsions might occur.

SYMPTOMS AND TREATMENT OF OVERDOSE:

Symptoms of poisoning include drowsiness, hypotension, muscular weakness and tremor, inco-ordination, headache, hallucination, palpitations, difficulty in micturition, restlessness, convulsions, hypertension, tachycardia.

Treament: In general the management of overdosage involves supportive and symptomatic therapy. Necessary measures should be taken to maintain and support respiration and circulation. In severe overdosage the stomach should be emptied by aspiration and lavage. Convulsions may be controlled by giving diazepam. For marked excitement or hallucinations chlorpromazine may be necessary. For severe hypertension, alpha-adrenoceptor blocking agent such as phentolamine or phenoxybenzamine and beta-blockers (propranolol HCl etc.) may be given. Tachycardia can be reated by beta-blockers.

EFFECT ON ABILITY TO DRIVE AND USE MACHINE:

TRIDIN-P might cause drowsiness, dizziness and blurred vision. Activities such as driving or operating machinery should be avoided.

PRECLINICAL SAFETY DATA:

Not applicable.

INSTRUCTION FOR USE:

For oral use only.

STORAGE CONDITIONS:

TRIDIN-P TABLETS:

Store below 30°C. Protect from heat and moisture.

TRIDIN-P SYRUP:

Store below 30°C. Protect from light, heat or freezing.

Keep the medicine out of reach of children / Jauhi dari kanak-kanak

DOSAGE FORMS AND PACKAGING AVAILABLE:

TRIDIN-P TABLETS:

Pack size : Blister pack : 100 x 10's

TRIDIN-P SYRUP:

Pack size : Plastic bottles : 60ml

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)
Plot 14, Lebuhraya Kampung Jawa,11900 Bayan Lepas,
Pulau Pinang, Malaysia.

DATE OF REVISION:

08/11/2017