Storage Condition:
Keep container tightly closed. Store in a dry place (below 30°C). Protect from light.

Pack Size:
Triprodine Tablet
Plastic container containing 30 tablets.

Triprodine Syrup
Plastic bottle containing 60ml, 90ml, 100ml and 120ml.

Product Registration Number:
Triprodine Tablet: MAL19860271AZ
Triprodine Syrup: MAL19860266AZ

Further information can be obtained from your doctor or pharmacist.

ROYCE®

Product Holder/ Manufactured by:
ROYCE PHARMA MFG SDN. BHD. 650435-X
PT 1663, Nilai Industrial Estate,
71800 Nilai, Negeri Sembilan, Malaysia.

Revision date:101016

ROYCE®

Triprodine Tablet and Syrup

(Triprolidine hydrochloride & Pseudoephedrine hydrocloride - Decongestant and antihistamine)

Presentation:
Triprodine Tablet - White, round tablets, diameter 8.7mm. Each tablet contains: Triprolidine Hydrochloride 2.5 mg and Pseudoephedrine Hydrochloride 60 mg.

Triprodine Syrup - Yellow lemon flavoured syrup. Each 5 ml measure contains: Triprolidine Hydrochloride 1.25 mg and Pseudoephedrine Hydrochloride 30 mg.

Indication:
Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory tract decongestant. Triprolidine provides antihistamine activity by antagonising H-receptors. For decongestion of the upper respiratory tract including the sinuses antra and Eustachian tubes in the common cold, hay fever, allergic and vasomotor rhinitis.

Dosage and Administration:
Adults and children over 12 years - One tablets or two 5 ml measures three times a day.
Children: 6 to 12 years - One 5ml measure three times a day.
2 to 5 years - Half a 5ml measure three times a day.
Use in the ederly: No specific studies have been carried out in the elderly. However, it may be advisable to monitor renal or hepatic function and if there is serious impairment then caution should be exercised.

Pharmacological Information:
Triprolidine HCl - Antihistamines antagonise the effects of histamine by selectively and competitively (competitive antagonism) occupying histamine H1 receptors on peripheral effects cells that normally respond to the endogenous agonist histamine. Also has anticholinergic and sedative properties.

It is readily absorbed from the gastro-intestinal tract, metabolised in the liver and excreted usually mainly as metabolites in the urine.

Pseudoephedrine HCl – It produces sympathomimetic effect by stimulating adrenergic receptor in the body. The drig provides vasoconstriction but does not posses broncholidation activity and is generally weaker in pressor and CNS effects than is ephedrine.

It is readily and completely absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine. It has half-life of several hours; elimination is enhanced and half-life accordingly shorter in acid urine.

Contraindication:
Contra-indicated in patients with known hypersensitivity to Pseudoephedrine or Triprolidine. Contra-indicated in persons under treatment with monoamine oxidase inhibitors, and within two weeks of stopping such treatment.

Warning:

(a) Not to be used in children less than 2 years of age.
(b) To be used with caution and doctor's /pharmacist's advice in children 2 to 6 years of age.

Precautions:
Although Pseudoephedrine causes virtually no press or effect in patients with normal blood pressure, Triprodine should be used with caution in patients with cardiovascular disorders, including hypertension. The effect of anti-hypertensive agents which modify sympathetic activity may be partially reversed by Triprodine. Caution should also be exercised in patients taking other sympathomimetic agents such as decongestant, appetite suppressants and amphetamine-like psychostimulants. The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.

As with other sympathomimetic agents, caution should be exercised in patients with prostatic enlargement or bladder dysfunction.

The antibacterial agent furazolidone is known to cause a progressive inhibition of monoamine oxidase and although there are no reports of hypertensive crises having occurred it should not be administered concurrently with Triprodine. Triprodine should be administered with caution in patients with severe hepatic or renal dysfunction.

Pregnancy and Lactation:
No data are available on the use of Triprolidine in human pregnancy. Pseudoephedrine and Triprolidine are excreted in breast milk.

Side Effects:
In some patients, Pseudoephedrine may occasionally cause insomnia. Rarely, sleep disturbance and hallucinations have been reported. Triprolidine may cause drowsiness. Patients should not drive a vehicle or operate machinery until they have determined their own response. In some patients the drowsiness induced by antihistamines may be potentiated by alcohol or other central sedatives. Fixed drug eruption due to Pseudoephedrine taking the form of nummular patches and linchenoid skin eruption due to triprolidine have been reported but these are rare events.

Symptoms and Treatment of Overdose:
Probable symptoms include drowsiness, inco-ordination, weakness, palpitation, irritability, hypertension, convulsions and difficulty in micturition. Gastric lavage and supportive measures for respiratory and circulation should be performed if indicated. Convulsion should be controlled with an anticonvulsant. Catheterisation of the bladder may be necessary. Alpha-adrenergic blockage may be required to treat hyper-rhythimias.

If desired the elimination of Pseudoephedrine can be accelerated by acid diuresis or by dialysis.