

## ACTICOL DM SYRUP

### DESCRIPTION:

A clear red colour syrup with raspberry flavour.

### COMPOSITION:

Each 5 ml contains:

Triprolidine Hydrochloride	1.25 mg
Pseudoephedrine Hydrochloride	30.0 mg
Dextromethorphan Hydrobromide	10.0 mg

### PHARMACODYNAMIC:

Pseudoephedrine is an orally effective upper respiratory tract decongestant. Pseudoephedrine is substantially less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system. Triprolidine is an antihistamine (H<sub>1</sub>-receptor). It acts by competing with histamine for H<sub>1</sub>-receptor sites on effector cells. It prevents, but does not reverse, responses mediated by histamine alone. It also has anticholinergic actions and provides a drying effect on the nasal mucosa.

Dextromethorphan is an antitussive. It suppresses the cough reflex by a direct action on the cough center in the medulla of the brain.

### PHARMACOKINETICS:

After the administration of 2.5 mg triprolidine hydrochloride and 60 mg pseudoephedrine hydrochloride to healthy adult volunteers, the peak plasma concentration ( $C_{max}$ ) of triprolidine is approximately 5.5 ng/ml - 6.0 ng/ml occurring at about 1.5 - 2.0 hours ( $T_{max}$ ) after drug administration. Its plasma half-life is approximately 3.2 hours. The  $C_{max}$  of pseudoephedrine is approximately 180 ng/ml with  $T_{max}$  approximately 1.5 - 2.0 hours after drug administration. The plasma half-life is approximately 5.5 hours (urine pH maintained between 5.0 - 7.0). The plasma half-life of pseudoephedrine is markedly decreased by acidification of urine and increased by alkalisation. Genetically controlled O-demethylation is the main determinant of dextromethorphan pharmacokinetics in human volunteers. It appears that there are two distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects.

### INDICATIONS:

ACTICOL DM SYRUP is indicated for the symptomatic relief of upper respiratory tract disorders which are benefited by a combination of a histamine H<sub>1</sub> receptor antagonist, a nasal decongestant and an antitussive

### CONTRAINDICATIONS:

Contraindicated in patients with a known hypersensitivity to pseudoephedrine, triprolidine or dextromethorphan.

Also contraindicated in patients under treatment with monoamine oxidase inhibitors or within two weeks of stopping such treatment. ACTICOL DM SYRUP is contraindicated in patients with severe hypertension or severe coronary artery disease.

ACTICOL DM SYRUP should not be administered to patients where cough is associated with asthma or where cough is accompanied excessive secretions.

The antibacterial agent furazolidone is known to cause a dose-related inhibition of monoamine oxidase. Although there are no reports of hypertensive crises caused by the

concurrent administration of ACTICOL DM SYRUP and furazolidone, they should not be taken together.

Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to patients in, or at risk of developing respiratory failure.

#### **SIDE EFFECTS:**

Drowsiness has been reported most frequently, central nervous system depression may occur. Rarely, sleep disturbances and hallucination have been reported. Dryness of the mouth, nose and throat; skin rashes, with or without irritation; and tachycardia have occasionally been reported. Urinary retention may occasionally occur in male patients in whose prostatic enlargement could be an important predisposing factor. Side effects attributed to dextromethorphan are uncommon; occasionally nausea, vomiting or gastrointestinal disturbance may occur.

#### **WARNING:**

Not suitable to be used in children below 2 years old.

For children between 2 to 6 years old – use with caution and follow the advice given by the doctor or pharmacist.

#### **PRECAUTIONS:**

Patients should not drive or operate machinery as ACTICOL DM SYRUP may cause drowsiness and impair performances in tests of auditory vigilance.

Although there are no objective data, patients should avoid concomitant use of alcohol or other centrally acting sedatives with ACTICOL DM SYRUP.

Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to patients in, or at risk of developing respiratory failure.

Although pseudoephedrine has virtually no pressor effect in patients with normal blood pressure ACTICOL DM SYRUP should be used with caution in patients taking antihypertensive agents, tricyclic antidepressants, other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psychostimulants. The effects of a single dose of ACTICOL DM SYRUP 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 diabetes, heart disease, hypertension, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

Caution should be exercised in the presence of severe renal or hepatic impairment and liver disease.

#### **USE IN PREGNANCY & LACTATION:**

Although pseudoephedrine, triprolidine and dextromethorphan have been in widespread use for many years without apparent ill consequence, there are no specific data on their use during pregnancy. Caution should therefore be exercised by balancing the potential benefit of treatment against any hazards. It has been estimated that approximately 0.5 to 0.7% of a single dose of pseudoephedrine ingested by a mother will be excreted in the breast milk over 24 hours, but the effect of this on breast-fed infants is not known. It is not known whether dextromethorphan or its metabolites are excreted in human milk.

#### **DRUG INTERACTIONS:**

Concomitant use of ACTICOL DM SYRUP with sympathomimetic agents, such as decongestants, tricyclic antidepressant, appetite suppressants, and amphetamine-like

psychostimulants or with monoamine oxidase inhibitors which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure. The pseudoephedrine content may potentially reverse the hypotensive action of drugs which interfere with sympathetic activity, including bretylinium, bethanidine, guanethidine, debrisoquine, methyl dopa and alpha and beta-adrenergic blocking agents.

**DOSAGE AND ADMINISTRATION:**

Adults and children over 12 years : 10 ml three times a day.

Children under 12 years: 6 – 12 years: 5 ml three times a day.

2 – 5 years : 2.5 ml three times a day.

*The elderly*

There have been no specific studies of ACTICOL DM SYRUP in the elderly. Experience has indicated that normal adult dosage is appropriate, although it may be advisable to monitor renal/hepatic function; if there is serious impairment then caution should be exercised.

**ROUTE OF ADMINISTRATION:**

Oral administration

**OVERDOSAGE & TREATMENT:**

Symptoms: May include drowsiness, lethargy, dizziness, ataxia, nystagmus, weakness, hypotonicity, respiratory depression, dryness of the skin and mucous membranes, tachycardia, hypertension, hyperactivity, hyperpyrexia, irritability, convulsions, difficulty with micturition, nausea and vomiting.

Treatment: Measures should be taken to maintain and support respiration and control convulsions. Gastric lavages should be performed up to 3 hours after ingestion if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis. Naloxone has been used successfully as a specific antagonist to dextromethorphan

**STORAGE CONDITIONS**

Store in a cool dry place below 30°C.

Keep the container tightly closed.

Protect from light.

Keep medicine out of reach of children.

**PRESENTATIONS:**

Bottles of 120 ml and 60 ml.

**MANUFACTURED BY:**

**NORIPHARMA SDN. BHD. (792633-A)**

Lot 5030, Jalan Teratai,

5 1/2 Mile Off Jalan Meru, 41050 Klang,

Selangor Darul Ehsan.

**DATE OF REVISION:**

September 2020