

## **CORIFED DM SYRUP**

### **DESCRIPTION:**

Red coloured syrup having raspberry flavour.

### **COMPOSITION:**

Each 5 ml contains:

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

### **ACTIONS & PHARMACOLOGY:**

Pseudoephedrine is an orally effective upper respiratory tract decongestant. It acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. It shrinks swollen nasal mucous membrane; reduces tissue hyperemia, edema and nasal congestion; and increases nasal airway potency. Drainage of sinus secretions may be increased and obstructed eustachian ostia may be opened.

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.

Pseudoephedrine is almost completely and rapidly absorbed from the G.I.T. Pseudoephedrine is incompletely metabolised in the liver. Onset of action is within 15 to 30 minutes and has a duration of action for 3 to 4 hours. Elimination is renal and about 75% is excreted unchanged. The rate of excretion is accelerated in acidic urine.

Triprolidine is absorbed from the G.I.T. The time to peak effect is 2 to 3 hours, half life of 3 to 3.3 hours, half life of 3 to 3.3 hours and a duration of action of 4 to 8 hours. It is metabolised in the liver and is excreted in the urine.

Dextromethorphan is absorbed from the G.I.T. The onset of action is usually within one-half hour and a duration of action up to 6 hours. It is rapidly and extensively metabolised to the active metabolite dextrophan in the liver. The unchanged drug and its metabolite are excreted in the urine.

### **INDICATIONS:**

Relief of unproductive cough accompanied by congestion of the upper respiratory tract including congestion with an allergic component.

### **CONTRAINDICATION:**

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. CORIFED DM SYRUP is contraindicated in patients with severe hypertension or severe coronary artery disease. CORIFED DM SYRUP should not be

administered to patients where cough is associated with asthma or where cough is accompanied excessive secretions.

### **SIDE EFFECTS:**

In some patients pseudoephedrine may occasionally cause insomnia. Rarely, sleep disturbances and hallucination have been reported. Triprolidine may cause drowsiness and patients should not drive a vehicle or operate machinery until they have determined their own responses. 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 erythematous nummular patches, and lichenoid skin eruption due to triprolidine, have been reported but both these reactions should be regarded as rare events.

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 & PRECAUTIONS:**

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 CORIFED 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 CORIFED 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 uncontrolled diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

Caution should be exercised in patients with hepatic and or renal impairment.

When used for treatment of cough and cold:

- (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.

### **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 0.75% of a single dose of pseudoephedrine and approximately 0.06 to 0.2% of a single dose of triprolidine 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:**

Because of its pseudoephedrine content, the effect of antihypertensive agents which modify sympathetic activity may be partially reversed by CORIFED DM SYRUP.

Toxic reactions can result from the combination of dextromethorphan with monoamine oxidase inhibitor like furazolidone.

Concomitant use of CORIFED DM SYRUP with sympathomimetic agents, such as decongestants, tricyclic antidepressants, 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 bretylium, bethanidine etc.

### **ROUTE OF ADMINISTRATION:**

Oral administration

### **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.

### **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, visual and auditory hallucinations, 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. 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

### **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:**

This medicine can impair cognitive function and can affect a patient's ability to drive safely.

**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 60ml and 120 ml

**MANUFACTURED BY:**

**NORIPHARMA SDN. BHD. 200701034604 (792633-A)**

Lot 5030, Jalan Teratai,

5 1/2 Mile Off Jalan Meru,

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**DATE OF REVISION:**

January 2022