

## DEXFEN SYRUP

**DESCRIPTION:** Orange coloured syrup having fruity flavour.

**COMPOSITION:** Each 5 ml contains dextromethorphan hydrobromide 15 mg.

**ACTION AND PHARMACOLOGY:** Dextromethorphan is an established antitussive agent which acts to relieve and suppress coughing.

Pharmacodynamics:

Dextromethorphan is a non-opioid antitussive drug. It exerts its antitussive activity by acting on the cough centre in the medulla oblongata, raising the threshold for the cough reflex.

Pharmacokinetics:

Following oral administration, dextromethorphan is well absorbed from the gut. Pharmacokinetic values are highly variable due to individual differences in the metabolism of dextromethorphan.

Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites dextrophan (also known as 3-hydroxy-N-methylmorphinan) 3-hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine. Dextrophan is the main metabolite which has antitussive action.

**INDICATIONS:** Indicated as an antitussive, for the control of non-productive cough or relief of persistent, dry, irritating cough.

**CONTRAINDICATIONS:** Dexfen syrup is contraindicated in patients with allergy/hypersensitivity to any of the ingredients of Dexfen syrup. It is also contraindicated in individuals who are taking, or have taken, monoamine oxidase inhibitors within the preceding two weeks. The concomitant use of a dextromethorphan-containing product and monoamine oxidase inhibitors, can occasionally result in symptoms such as hyperpyrexia, hallucinations, gross excitation or coma.

**SIDE EFFECTS:** Generally minimal side effects at recommended dosage. Occasionally, drowsiness, dizziness, excitation, mental confusion and gastrointestinal disturbance.

**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 with high fever, skin rash (allergy), headache, nausea or vomiting should consult a physician. It should be used with caution in patients with liver disease. Do not take Dexfen syrup for chronic cough or chronic cough due to heavy smoking, emphysema, asthma or if cough is accompanied by excessive phlegm (mucus).

Pregnancy & Lactation: Although dextromethorphan has been in widespread use for many years without apparent ill consequence, there is insufficient information on the effects of administration during human pregnancy. It is not known whether dextromethorphan or its metabolites are excreted in breast milk. Therefore, it should only be used when the potential benefit of the treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

Drug interaction: Dextromethorphan hydrobromide may interact with MAOIs. The concomitant use of a dextromethorphan-containing product and monoamine oxidase inhibitors can occasionally result in symptoms such as hyperpyrexia, hallucinations, gross excitation or coma.

**DOSAGE AND ADMINISTRATION**

**Adults and children over 12 years:**

30 mg (or 10ml) every 6 to 8 hours, to a usual maximum of 120 mg (or 40ml) in 24 hours.

**Children aged 6 to 12 years:**

15 mg (or 5ml) every 6 to 8 hours to a maximum of 60 mg (or 20ml) in 24 hours.

**OVERDOSAGE AND TREATMENT:** Overdosage may lead to drowsiness, excitation, confusion, lethargy, nystagmus, ataxia, respiratory depression, nausea, vomiting, and hyperactivity. There is no specific antidote for an overdose, therefore, treatment of the patients consist of symptomatic and supportive therapy.

**PRESENTATION:** Bottle of 120 ml and 60ml.

**STORAGE:** Store in a dry place below 30°C. Keep container tightly closed. Protect from light. Keep out of reach of children. Shelf-life: 3 years.

**MANUFACTURED BY:** Noripharma Sdn. Bhd  
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