Dextromethorphan Syrup

This information is a summary only. It does not contain all information about this medicine. If you would like more information about the medicine you are taking, check with your doctor or other health care provider. No rights can be derived from the information provided in this medicine leaflet.

Qualitative and quantitative composition

Dextromethorphan Hydrobromide

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 10ml dose.

Contains 3.07g sucrose per 5ml dose, to be taken into account with diabetes

Therapeutic indications
For the symptomatic relief of non-productive coughs such as those associated with the common cold and bronchitis.

Posology and method of administration

Oral.

Recommended doses
Adults and children over 12 years: 10ml.

Elderly: as adults dose with caution.

Dosage schedule
The dose may be repeated after 4 hours if required.

Contraindications
Contraindicated in patients with liver disease and/or known hypersensitivity to dextromethorphan hydrobromide, and menthol. Patients being treated with monoamine oxidase inhibitors should avoid using the product. Persistent or productive cough. Dextromethorphan should not be administered to patients in or at risk of developing respiratory failure or during an acute asthma attack. Do not use within 2 weeks of discontinuation of MAOI use.

Children under 12 years of age.

Special warnings and precautions for use
Do not exceed the stated dose.

Keep all medicines away from children.

If symptoms persist consult your doctor.

Dextromethorphan normally works without causing drowsiness, but care should be taken initially as rare exceptions can occur.

Use with caution in a history of asthma.

Label states: Consult a doctor or pharmacist before use if you have a history of asthma.

Do not give to children under 12 years.

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 10ml dose.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Contains 3.07g sucrose, to be taken into account in people with diabetes.

Interaction with other medicinal products and other forms of interaction
Cimetidine may delay the elimination of dextromethorphan. It is therefore imperative that the dose of Dextromethorphan is not exceeded when it is taken with other medicines. Dextromethorphan interacts with MAOI's.

Pregnancy and lactation
There is no evidence of safety in human pregnancy. However, the drugs in the formulation have been widely used for many years without apparent ill consequence. No information is available on the excretion of dextromethorphan or its metabolites in breast milk. It is therefore best avoided during breastfeeding.

Effects on ability to drive and use machines
At the stated dose, no evidence has been found that the formulation has any effect on the ability to drive or use machinery however dextromethorphan hydrobromide may cause dizziness and drowsiness rarely.

Undesirable effects
At the stated dose constipation, gastrointestinal discomfort, nausea, vomiting, dizziness and drowsiness may occur rarely.

Overdose
Serious overdoses have been reported with other dextromethorphan containing products. Taken in large doses, may cause drowsiness, dizziness, excitation, nausea, vomiting, gastro intestinal disturbance, blurred vision, nystagmus, ataxia, urinary retention, stupor, coma, facial oedema and urticaria. Very large doses may produce respiratory depression and some patients may be particularly sensitive to this. This may be combatted with trial small doses (1.5 - 3UG/KG to be repeated only if there is a response) of morphine antagonists such as naloxone. Symptoms arising from oral poisoning with menthol are, severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness and coma.

Treatment of overdose: acutely, gastric lavage: otherwise, general supportive measures should be used.

Dependence has been reported occasionally with dextromethorphan.

Pharmacodynamic properties
Pharmacotherapeutic Group: Cough suppressant and expectorants, Combinations

Dextromethorphan acts as a non-narcotic cough suppressant. The drug acts centrally to elevate the threshold for coughing.

Menthol relieves irritation, diminishes congestion, and checks excessive secretion of mucous membranes in the upper respiratory tract and is used for the treatment of the symptoms of bronchitis.

Pharmacokinetic properties
Dextromethorphan is fully absorbed from the gastro-intestinal tract and passes via the portal vein to the liver before entering the general circulation. Dextromethorphan has three metabolites, principally dextrorphan which has approximately the same antitussive potency as dextromethorphan itself. Dextromethorphan is not metabolised to either morphine or codeine. In general, approximately 50% of dextromethorphan plus metabolites is excreted in the urine within 24 hours. Plasma levels of therapeutic doses are very low, due to metabolism in the liver. Plasma levels of the principal metabolite, dextrorphan, are higher than dextromethorphan, plasma levels reaching a peak 2 hours after administration. The plasma half life of dextrorphan has been determined as approximately 0.5-1.0 hour in the dog.
After absorption menthol is excreted in the urine and bile as a glucuronide.

Special precautions for storage
Store below 25°C.

Lagaay International BV
Van Helmontstraat 99
3029 AA Rotterdam, The Netherlands
Tel: +31 - 10 4123871