Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Benylin Dry Coughs 7.5mg/5ml Syrup (dextromethorphan hydrobromide) Product Information

Presentation:
Brown syrup containing 7.5mg dextromethorphan hydrobromide per 5ml.
Each 5ml also contains: Sucrose 1.6g, Liquid glucose 2.38g, Sorbitol 325mg, Ethanol 236 mg, Sodium benzoate 25 mg, Propylene glycol 2.715 mg.
Uses:
This product is indicated as an antitussive, for the relief of an unproductive cough.
Dosage:
Adults: 10ml four times daily.
Contraindications:
Use in children under 12 years. Known hypersensitivity to ingredients.
Dextromethorphan should not be used in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs and the concomitant use of these medications may cause a rise in blood pressure and/or hypertensive crisis.
Precautions:
Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions. Caution in hepatic impairment.
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g. major depression). Drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate. Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including MAOIs) and CYP2D6 inhibitors. If serotonin syndrome is suspected, treatment with this medicine should be discontinued. Do not take with other cough and cold medicines. Use of dextromethorphan with alcohol or other CNS depressants may

increase the effects on the CNS and cause toxicity in relatively smaller doses. While taking this product, patients should be advised to avoid alcoholic drinks and consult a healthcare professional prior to taking with central nervous system depressants.
Caution in patients who are slow metabolisers of CYP2D6 or use CYP2D6 inhibitors.
Caution in atopic children due to histamine release.
Caution due to the following excipients:

- This product contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- This medicine contains 650 mg sorbitol in each 10 ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
- This medicine contains 50 mg benzoate salt in each 10 ml dose. This medicine contains 5.43 mg propylene glycol in each 10 ml dose.
- This medicine contains 472 mg of alcohol (ethanol) in each 10 ml dose. The amount in of this medicine is equivalent to 12 ml beer or 5 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines.

See SPC for further precautions

Pregnancy and lactation:
There are no adequate and well-controlled studies in pregnant women. It is not known whether dextromethorphan or its metabolites are excreted in breast milk. Dextromethorphan should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing foetus or nursing infant.
Side effects:
Angioedema, pruritus, rash, urticaria, insomnia, agitation, confusional state, seizure, dizziness, psychomotor hyperactivity, somnolence, respiratory depression, abdominal pain, diarrhoea, gastrointestinal disorder, nausea, vomiting**,** drug dependence and drug withdrawal syndrome.
RRP (ex-VAT): 150 ml £6.24
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL Number: 15513/0051
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