

Package leaflet: Information for the user



Non-Drowsy Dry Coughs Syrup

dextromethorphan hydrobromide 7.5 mg/ 5 ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side-effects, talk to your doctor or pharmacist. This includes any possible side-effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

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2. What you need to know before you use Benylin Non-Drowsy Dry Coughs Syrup
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1 What Benylin Non-Drowsy Dry Coughs Syrup is and what it is used for

Benylin Non-Drowsy Dry Coughs Syrup is a medicine which is used to help relieve dry, irritating coughs. The liquid contains dextromethorphan hydrobromide which is an antitussive to help stop persistent coughing.

The medicine is for use in adults and children aged 12 years and over.

2 What you need to know before you use Benylin Non-Drowsy Dry Coughs Syrup

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

This medicine can lead to dependence. Therefore the treatment should be of short duration

X Do not use Benylin Non-Drowsy Dry Coughs Syrup ...

- If you have ever had a **bad reaction** to dextromethorphan or any of the other ingredients.
- If you suffer from **lung disease**.
- If you are taking, or have taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
- If you are taking selective serotonin re-uptake inhibitors (used to treat **depression** and **anxiety** such as fluoxetine, paroxetine and sertraline).
- For children under 12 years old.

If any of these apply to you, **get advice from a doctor or pharmacist without using Benylin Non-Drowsy Dry Coughs Syrup.**

! Warnings and precautions

Talk to your doctor or pharmacist before taking Benylin Non-Drowsy Dry Coughs Syrup

- If you suffer from **liver** problems.
 - If you have **bronchitis, emphysema** or **asthma** or have had a **cough for a few weeks** or a **cough with a lot of mucus (phlegm)**.
 - If you have **alcohol dependence**.
 - If you have a history of **drug abuse**.
 - If you have been told by your doctor that you are a **slow metabolizer of CYP2D6**.
 - If you are taking medicines such as certain antidepressants or antipsychotics. Benylin Non-Drowsy Dry Syrup may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).
 - If you are taking any other **cough and cold medicines**.
 - If your child is prone to developing certain allergic reactions (e.g. **atopic reactions**).
- Avoid alcoholic drink when taking this medicine.

! Other medicines and Benylin Non-Drowsy Dry Coughs Syrup

Talk to your doctor or pharmacist before taking Benylin Non-Drowsy Dry Coughs Syrup if are taking any other **medicines**, including:

- Certain **drugs for depression** such as norepinephrine-dopamine reuptake inhibitors (NDRI), which include bupropion.
- **Antipsychotics** (drugs used to treat **mood disorders** such as haloperidol, thioridazine, perphenazine).
- **Anti-arrhythmic agents** (drugs used to treat **an irregular heartbeat** such as amiodarone, propafenone, quinidine and flecainide).
- **Calcimimetic agents** (drugs used to treat **secondary hyperparathyroidism**, elevated parathyroid hormone levels such as cinacalcet).
- **Metoprolol** (drug used to treat **high blood pressure, chest pain or fast heartbeat**).
- **Anti fungals** (terbinafine, isavuconazole).
- **Opioid analgesics** (drugs used to relieve pain e.g. codeine, tramadol, morphine, methadone).
- **Antihistamines** (drugs used to treat the symptoms of **allergic reactions**).
- **Hypnotics (sleeping tablets** including barbiturates).
- Tranquilizers** (drugs used to **relax muscles** or **decrease anxiety**).
- Do not take this medicine if you are taking any medicines listed in the 'Do not use this medicine' section of this leaflet.

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

! Pregnancy and Breastfeeding

■ If you are pregnant or breast-feeding, only use this medicine on the advice of your doctor.

! Driving and using machines

This medicine may cause drowsiness or dizziness. If affected, do not drive or operate machinery. Avoid alcoholic drink.

! Benylin Non-Drowsy Dry Syrup contains sucrose, sorbitol, liquid glucose, ethanol and sodium

■ This medicine contains 3.2 g of sucrose per 10ml dose, 4.76 g of glucose per 10 ml dose and invert sugar. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. ■ This medicine contains 650mg sorbitol in each 10ml dose. Sorbitol is a source of

fructose. If your doctor has told you (or your child) that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

■ This medicine contains 472 mg of alcohol (ethanol) in each 10ml dose. The amount in each 10ml dose of this medicine is equivalent to 12 ml beer or 5 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

■ This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'.

■ This medicine contains 42 mg benzoate salt in each 10 ml dose.

■ This medicine contains 5.43 mg propylene glycol in each 10ml dose.

3 How to take Benylin Non-Drowsy Dry Coughs Syrup

Check the table below to see how much medicine to take

- For oral use only
- Do not take more medicine than the label tells you to.

! Children under 12 years

Do not give to children under 12 years.

! Adults and children aged 12 years and over

Age	Dose
Adults and children aged 12 years and over	Take two 5 ml spoonfuls four times a day.

■ Do not take more than 4 doses in 24 hours.
■ If symptoms persist or worsen, talk to your doctor or pharmacist.

! If anyone has too much

If you take more Benylin Non-Drowsy Dry Coughs Syrup than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Also, other types of hallucinations, clumsiness, dizziness, speech problems, lack of energy, high blood pressure,

tremor, constricted or dilated pupils, difficulty passing urine, or sudden abdominal pain or rectal bleeding due to inflammation of the colon (ischaemic colitis). Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions.

Contact your doctor or hospital straight away if you experience any of the above symptoms.

! If you forget to take the medicine

If you forget to take a dose, take the next dose when needed provided that the last dose was taken at least 4 hours ago. **Do not** take a double dose.

4 Possible side-effects

Like all medicines Benylin Non-Drowsy Dry Coughs can cause side-effects, although not everybody gets them.

If you experience any of the following stop using this medicine and seek immediate help:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Fits.

If you experience any of the following stop using this medicine and talk to your doctor:

Rare (may affect up to 1 in 1000 people)

- Difficulty in breathing
- Feeling confused.

Other effects which may occur but it is not known how often, include:

- Upset stomach, stomach pain or diarrhoea.
- Nausea or vomiting.
- Dizziness or drowsiness.
- Feeling agitated, jittery, or restless.
- Difficulty sleeping (insomnia).
- Shallow breathing.

Reporting of side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. You can also report

side effects directly in Malta via ADR Reporting at: www.medicinesauthority.gov.mt/adrportal.

By reporting side-effects you can help provide more information on the safety of this medicine.

5 How to store Benylin Non-Drowsy Dry Coughs Syrup

Do not store above 30°C.

Keep the bottle tightly closed in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Benylin Non-Drowsy Dry Coughs Syrup contains:

The active ingredient in 5 ml of Benylin Non-Drowsy Dry Coughs Syrup is: 7.5 mg Dextromethorphan hydrobromide.

Other ingredients are: Sorbitol solution (70%) E420, glycerol, sucrose, liquid glucose, citric acid monohydrate, sodium benzoate (E211), caramel T12 (containing sucrose, glucose and invert sugar), saccharin sodium, imitation peach flavour (containing ethanol, propylene glycol), levomenthol, ethanol (96% v/v), carbomer and purified water.

What the medicine looks like and contents of the pack

Benylin Non-Drowsy Dry Coughs Syrup is a pale brown coloured, peach flavoured syrup, available in 30 ml, 125 ml and 300 ml glass bottles. Not all pack sizes may be marketed.

Marketing Authorisation holder and Manufacturer

Product Authorisation Folder: Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer: Delpharm Orleans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

This leaflet was revised

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