

Package leaflet: Information for the user

Benylin Dry Coughs Syrup

Diphenhydramine hydrochloride 14 mg/5 ml

Dextromethorphan hydrobromide 6.5 mg/5 ml

Levomenthol 2 mg/5 ml

Read all of this leaflet carefully before you start taking 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 feel worse after 5 days.

What is in this leaflet

1. What Benylin Dry Coughs Syrup is and what it is used for
2. What you need to know before you use Benylin Dry Coughs Syrup
3. How to use Benylin Dry Coughs Syrup
4. Possible side-effects
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6. Contents of the pack and other information

1 What Benylin Dry Coughs Syrup is and what it is used for

Benylin Dry Coughs is a medicine which is used to help relieve dry, irritating coughs. The liquid contains diphenhydramine hydrochloride which is an antihistamine that helps relieve coughing and dry secretions in the nose and chest, dextromethorphan hydrobromide which is an antitussive to help stop coughing and levomenthol which helps you breathe more easily by relieving congestion.

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

2 What you need to know before you take Benylin 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.

Do not use Benylin Dry Coughs Syrup

- If you are allergic to diphenhydramine, dextromethorphan, levomenthol or any of the other ingredients of this medicine (listed in section 6).
- 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 Dry Coughs Syrup**.

Warnings and Precautions

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

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

- If you suffer from **liver** or **kidney 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 your child is prone to developing certain allergic reactions (e.g. **atopic reactions**).
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you are **susceptible to glaucoma** (increased pressure in the eye).
- If you are taking any other **cough and cold medicines**.
- If you are using any other medicines containing **diphenhydramine**.
- 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 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).

Other medicines and Benylin Dry Coughs Syrup

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

- *antihistamines* (drugs used to treat the symptoms of **allergic reactions**).
- *tricyclic antidepressants* (drugs to treat **mood disorders**).
- *anticholinergic drugs* (drugs used to treat **cramps** and **spasms** such as atropine).
- *hypnotics* (**sleeping tablets** including barbiturates).

- *tranquillisers* (drugs used to **relax muscles** or **decrease anxiety**).
- *opioid analgesics* (drugs used to **relieve pain** e.g. codeine, tramadol, morphine, methadone).
- *antipsychotics* (drugs used to treat **mood disorders** such as haloperidol, thioridazine, perphenazine).
- Certain **drugs for depression** such as norepinephrine/dopamine reuptake inhibitors (NDRIs), which include bupropion.
- *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).
- *Antifungals* (terbinafine, isavuconazole).
- *Metoprolol* (drug used to treat **high blood pressure, chest pain or fast heartbeat**).
- 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 the bullet points apply to you now or in the past, **talk to a doctor or pharmacist**.

Pregnancy and breast-feeding

- 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. If affected, do not drive or operate machinery.

Avoid alcoholic drink.

Benlyn Dry Coughs Syrup contains

sucrose, liquid glucose, invert sugar, ethanol, Ponceau 4R (E124), propylene glycol (E1520), benzyl alcohol, sodium benzoate and sodium

- This medicine contains sucrose, liquid glucose and invert sugar. 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 should be taken into account in patients with diabetes mellitus.
- This medicine contains 392 mg of alcohol (ethanol) in each 10 ml dose. The amount in 10 ml of this medicine is equivalent to less than 10 ml beer or 4 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- The colouring, Ponceau 4R (E124) in this medicine may cause allergic reactions.
- This medicine contains 33.4 mg sodium (main component of cooking/table salt) in each 10 ml dose. This is equivalent to 1.67 % of the recommended maximum daily dietary intake of sodium for an adult.

- This medicine contains 0.96 mg benzyl alcohol in each 10 ml dose. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”). Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- This medicine contains 16.8mg benzoate salt in each 10 ml dose.
- This medicine contains 5.21 mg propylene glycol in each 10ml dose.

3 How to use Benylin Dry Coughs Syrup

Check the table that follows to see how much medicine to take.

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

Children under 12 years

Do not give to children under 12 years old.

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 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, this medicine can cause side-effects, although not everybody gets them.

If you experience any of the following stop using this medicine and seek immediate medical 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.
- Hallucinations or fits.

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

- Sleep disturbances.
- A fast or irregular heartbeat or an increased awareness of the heartbeat (palpitations).
- Trouble passing water (especially in men with prostate problems).

Other effects which may occur include:

Very common (may affect more than 1 in 10 people)

- Drowsiness.

Common (may affect up to 1 in 10 people)

- Thickened mucus, dry mouth or throat.
- Dizziness or headache.
- Feeling jittery.
- Blurred vision.
- Upset stomach.
- Unusual weakness.

Uncommon (may affect up to 1 in 100 people)

- Confusion, difficulty sleeping, irritability, nervousness or agitation.
- Tinnitus (a persistent noise in the ears).
- Difficulty in breathing.
- Nausea or vomiting.

Rare (may affect up to 1 in 1000 people)

- Depression.
- Tremors, uncontrollable movements or low blood pressure.
- Abnormal blood or liver function tests that could indicate a blood or liver disorder.

Other effects which may occur but it is unknown how often

- Difficulty performing tasks, or pins and needles.
- Chest discomfort or shallow breathing.
- Stomach pain constipation, diarrhoea or indigestion.
- Dry nose.
- Pain when passing water.

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.

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

5 How to store Benylin Dry Coughs Syrup

Keep this medicine tightly closed and store in the original container.

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

Do not store above 30°C.

Discard this medicine 4 months after first opening the bottle.

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 Dry Coughs Syrup contains:

The active ingredients in 5ml of Benylin Dry Coughs syrup is:

14 mg Diphenhydramine hydrochloride, 6.5 mg Dextromethorphan hydrobromide and 2 mg Levomenthol.

Other ingredients are: Liquid glucose, sucrose, invert sugar, ethanol, glycerol, sodium citrate, saccharin sodium, citric acid monohydrate, sodium benzoate (E211), caramel (E150) (containing

sucrose, glucose and invert sugar), raspberry flavour (containing propylene glycol (E1520), ethanol and benzyl alcohol), carbomer, Ponceau 4R (E124) and water.

What the medicine looks like and the contents of the pack

Benylin Dry Coughs is a clear red syrup, darkening on aging to brown syrup available in 125 ml glass bottles.

Marketing Authorisation Holder:

JNTL Consumer Health I (Ireland) Ltd.

Block 5, High Street, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised in

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