

Project Name / Design	IE_Benlylin Dry Coughs Syrup 125ml_PIL_Picasso_2058		
New Component / Item Code	XXXXXX	ArtWorks ID	EMEA_2020_00028313_000
Old Component / Item Code	LN508003	Languages	Ireland
Product / Eurocode / Mat. ID Code	5162313	Job / Version No.	402020279_r0
		Date	21-08-2020

PANTONE 2735 C

ELITHO OFFSET

REPRESENTATION: Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

Reference	NOTC010	Security Code / ICFP	XXXXX
-----------	---------	----------------------	-------

TECHNICAL DETAILS

Component	Leaflet	Plant	Delpharm Orléans
Dimensions	160 x 210 mm	Master Dieline	JJDEL_00043_V1
		Date	14-05-2020

SCHAWK!

Fonts used	Bliss-Bold	Smallest Text Size
	Bliss2-Heavy	6.0pt
	Humanist521BT-Bold	Ave. Text Size
	Humanist521BT-Italic	6.75pt
	Humanist521BT-Roman	Largest Text Size
	16.0pt	

Package leaflet: Information for the user



Dry Coughs Syrup

Diphenhydramine hydrochloride 14 mg/5 ml
Dextromethorphan hydrobromide 6.5 mg/5 ml
Levomethol 2 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

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

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

Benlylin 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 use Benlylin 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 Benlylin 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 Benlylin Dry Coughs Syrup.**

⚠ Warnings and Precautions

Talk to your doctor or pharmacist before taking Benlylin 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. Benlylin 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 Benlylin 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 **irregular heart beats** such as amiodarone, propafenone, quinidine and flecainide).
- **Calcimimetic agents** (drugs used to treat **secondary hyperparathyroidism**, elevated parathyroid hormone levels such as cinacalcet).
- **Anti-fungals** (terbinafine).
- 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.**

⚠ Benlylin Dry Coughs Syrup contains sucrose, liquid glucose, ethanol, Ponceau 4R and sodium

- This medicine contains sucrose and liquid glucose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product. Contains 3.5 g glucose and 1 g sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.

turn over ►

- This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per 5 ml, equivalent to 5 ml beer, 2 ml wine per 5 ml. This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.
- The colouring, Ponceau 4R (E124) in this medicine may cause allergic reactions.
- This medicinal product contains 16.7 mg sodium per 5 ml. To be taken into consideration by patients on a controlled sodium diet.

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.

i Children under 12 years

Do not give to children under 12 years old.

i 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.

A 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.

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.

A 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, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517

Website: www.hpra.ie;

Email: medsafety@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.

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 5 ml 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, ethanol, glycerol, sodium citrate, saccharin sodium, citric acid monohydrate, sodium benzoate (E211), caramel (E150), raspberry flavour, 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, available in 125 ml glass bottles.

Marketing Authorisation Holder: Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised in August 2020.

Benylin is a registered trade mark.

XXXXXX