



Dual Action Dry Syrup

Pseudoephedrine 30 mg, Dextromethorphan 10 mg, triprolidine 1.25 mg
Cough & Congestion

- This medicine is used to help relieve symptoms of cold and flu including irritating dry cough and related congestion symptoms.
- This medicine is for use by adults and children aged 12 years and over.
- **Do not use this medicine:**
 - There are some people who should not use this medicine. To find out if you are one of them See Section 2 ►
 - If you have ever had a **bad reaction** to any of the ingredients. For the list of ingredients See Section 6 ►
- **Speak to your doctor:**
 - If you suffer from any of the conditions mentioned in Section 2. See Section 2 ►
 - If you are taking any **other medicines**. See Section 2 ►
- **Follow the dosage instructions carefully.** These are shown in the tables. See Section 3 ►

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

Ask your pharmacist if you need more information or advice.

Go to see your doctor if your symptoms worsen or do not improve after a few days.

What the medicine is for

Benylin Dual Action Dry is a medicine which is used to help relieve dry coughs and related congestion symptoms. The liquid contains triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes, pseudoephedrine hydrochloride which is a decongestant that unblocks stuffy noses and dextromethorphan hydrobromide which is an antitussive to help stop coughing.

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

Before taking this medicine

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.



X Do not use this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If you have **high blood pressure** or **heart disease**.
- If you are taking beta blockers (used to treat **high blood pressure**).
- 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 drugs for depression such as **selective serotonin reuptake inhibitors** (SSRIs) such as fluoxetine, paroxetine and sertraline.
- If you are taking **furazolidone** (an antibacterial agent).
- If you have had a **cough** for a few weeks, or a cough which brings up any blood or a lot of mucus that may be caused by **asthma** or other serious breathing difficulties.
- If you are taking any other cough and cold medicine.
- If you have diabetes.
- If you have an overactive thyroid.
- If you suffer from, or have had closed angle glaucoma (increased pressure in the eye).
- If you have pheochromocytoma (rare tumour which affects your heart rate and blood pressure).
- If you have severe kidney problems.
- For children under 12 years old.
- This medicine should not be used to sedate a child.

If any of these apply to you, **get advice from a doctor or pharmacist without using Benylin Dual Action Dry.**

A Talk to your doctor or pharmacist...

- If you suffer from **liver** or **kidney problems**.
- If you are susceptible to **glaucoma** (increased pressure in the eye).
- If you have difficulty **breathing** (emphysema) or **chronic bronchitis**.
- If you suffer from a chronic or persistent cough, if you have **asthma**, suffer from asthma attacks or where cough is accompanied by excessive secretions.
- If you have **prostate problems** (difficulty with passing water or needing to pass water often).
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you are taking **alcohol**.
- If your child is prone to developing certain **allergic reactions** (e.g. atopic reactions) due to histamine release (a chemical that is released within the body during an allergic reaction).
- If you have a history of drug abuse.
- If you have been told by your doctor that you are a slow metabolizer of CYP2D6.

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines such as:
 - **Sedatives** (drugs used to treat **anxiety** and **tension**).
 - Certain **drugs for depression** such as norepinephrine-dopamine reuptake inhibitor (NDRI), which include bupropion and tricyclic antidepressants (used to treat mood disorders).
 - **Moclobemide** (used to treat **mood disorders**).
 - **Cardiac glycosides** (drugs used to control **heart rhythms** or **contractions** e.g. digoxin).
 - **Ergot alkaloids** (drugs used to treat **migraine** such as ergotamine and methysergide).
 - **Oxytocin** (drug used to help **contractions** during childbirth).
 - **Hypnotics** (sleeping tablets including **barbiturates**).
 - **Opioid analgesics** (drugs used to relieve **pain** e.g. codeine, tramadol, morphine, methadone).
 - **Antipsychotics** (drugs used to treat **mood disorders** e.g. haloperidol, thioridazine, perphenazine).
 - **Antihistamines** (drugs used to treat **allergies**).
 - **Sympathomimetic drugs** (stimulants or appetite suppressants and drugs used to treat **congestion** and **asthma**).
 - **Antihypertensives** (drugs used to treat **high blood pressure** such as guanethidine, methyldopa, adrenergic neuron blockers, beta blockers, debrisoquine, bretylium and betanidine).
 - **Anti-arrhythmic agents** (drugs used to treat **irregular heartbeat** such as amiodarone, propafenone, flecainide and quinidine).
 - **Halogenated anaesthetics agents** (such as chloroform, cyclopropane, halothane, enflurane or isoflurane).
 - **Calcimimetic** (drugs used to treat **secondary hyperparathyroidism**, elevated parathyroid hormone levels such as cinacalcet).
 - **Anti-fungals** (terbinafine).

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.**

A If you are pregnant or breast-feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

A Special warnings about this medicine

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

A If any of the following occur this product should be stopped:

- Hallucinations.
- Restlessness.
- Sleep disturbances.

turn over ►

Some of the ingredients can cause problems

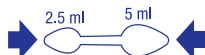
- Each 5 ml of this medicine contains 2.8 g of sucrose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains 5% v/v ethanol (alcohol), which is up to 190 mg per 5 ml, equal to 5 ml beer or 2 ml wine per 5 ml. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease and epilepsy.
- Methyl hydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may happen after a few days.
- Sodium benzoate (E211) which may irritate the skin, eyes and mucosal surfaces.
- The colouring in this medicine may cause allergic reactions. These reactions are more common in people who are allergic to aspirin.

3 How to take this medicine

Check the tables below to see how much medicine to take.

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not take more than the stated dose shown in the table.
- Do not overfill the spoon.

There is a double-ended spoon in the pack.



Adults and Children over 12 years old

Age	Dose
Adults and children over 12 years old	Take two large 5 ml spoonfuls every 4 - 6 hours, up to 4 times a day.

- Do not take more than 4 doses in 24 hours.
- Leave at least 4 hours between doses.
- If symptoms persist talk to your doctor or pharmacist.

If anyone has too much

If anyone has too much contact your doctor or pharmacist immediately.

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 taking this medicine and talk to your doctor:

- A few people have had hallucinations, delusions and fits.
- Skin rashes that are sometimes itchy.
- Allergic reactions including skin rashes (which may be severe and include blistering and peeling of the skin).
- Swelling of the face, lips mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- A few people may find their heartbeat increased or increased awareness of the heartbeat (palpitations).
- Shortness of breath.
- A few men, especially men with prostate problems, may have trouble passing water.
- Nausea, vomiting and upset stomach.
- Restlessness or sleep disturbances.

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

- Headache.

Common (may affect up to 1 in 10 people)

- Difficulty sleeping, nervousness or dizziness.
- Dry mouth, nausea, upset stomach or thickened mucus.
- Drowsiness.
- Blurred vision.
- Difficulty performing tasks.
- Paradoxical drug reaction (opposite effect than which would normally be expected).

Rare (may affect up to 1 in 1000 people)

- Confusion, depression, tremor.
- Low blood pressure.
- Blood disorder.
- Sleep disorder.
- Liver problems.
- Unusual movements (extrapyramidal disorder).

Other effects which may occur but it is unknown how often:

- Agitation, irritability, feeling anxious, jittery or feelings of extreme happiness.
- Pins and needles.
- Increased blood pressure.
- Dry throat or nose bleeds (epistaxis).
- Stomach pain or discomfort, diarrhoea or vomiting.
- Fatigue.
- Pain when passing water.
- This product may potentiate the effects of alcohol and other central nervous system depressants.

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 the medicine.

5 Storing this medicine

Do not store this product above 25°C.

Keep this medicine in the outer carton and do not refrigerate. Keep this medicine tightly closed in the original container. 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 Further Information

What's in this medicine?

The active ingredients in 5 ml of Benlyn Dual Action Dry are: Triprolidine hydrochloride 1.25 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg.

Other ingredients are: Sorbitol, sucrose, sodium benzoate (E211), methyl hydroxybenzoate (E218), ponceau 4R (E124), alcohol, blackberry flavour, levomenthol, vanillin and purified water.

What the medicine looks like

Benlyn Dual Action Dry is a clear red liquid available in 100 ml bottles.

The Product Authorisation Holder: McNeil Healthcare (Ireland) Ltd., Airtown Road, Tallaght, Dublin 24, Ireland.

The Manufacturer: Famar Orleans, 5 avenue de Concy, 45071 Orleans, Cedex 2, France

This leaflet was revised December 2016.

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Healthcare (Ireland) Ltd.

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Orleans - Artworks Center

Change Artwork Color

Client	JNJ		
Change request #	CRD 0XXX		
Product	BENYLIN DUAL ACTION DRY 100ML IE		
Component #	LN50XX01		
Old component #	F310533		
ATW version	9.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix LN50XX01		
Client code	16-0647		
Main font type	Humanist 521 BT		
Minimum font size	7.5 pts		
Colours			
Recto 1	Verso 1	Recto 2	Verso 2
PMS 2735	PMS 2735		
PMS 3272	PMS 3272		

A print out of this artwork should not be used for exact colour matching but to check if the layout, spelling, text and colour references are correct. Please check thoroughly.