

Dual Action Dry Syrup

Pseudoephedrine 30mg, Dextrométhorphan 10mg, 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.

I 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 26 B

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.

2 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 very high blood pressure or severe heart 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 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 any of these apply to you, get advice from a doctor or pharmacist without using Benylin Dual Action Dry.

Talk to your doctor or pharmacist...

- If you intend to give to a child under 12 years old.
- If you suffer from liver or kidney problems.
- If you have high blood pressure or heart disease.
- If you have diabetes or have been told by your doctor that you have an intolerance to some sugars.
- If you have glaucoma (increased pressure in the eye).
- If you have an overactive thyroid gland.
- If you have prostate problems (difficulty with passing water or needing to pass water often).
- If you are taking any other medicines, including:

- Sedatives (drugs used to treat **anxiety** and **tension**).
- Tricyclic antidepressants (used to treat mood disorders).
- 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, alpha and beta blockers, debrisoquine, bretylium and betanidine).

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.**

Alf you are pregnant or breast-feeding

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

Special warnings about this medicine

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

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 breastfeeding 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	Dosage
Adults and	Take two large 5 ml
children over	spoonfuls every 4 - 6
12 years old	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.

Alf anyone has too much

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

Alf 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

Benylin Dual Action Dry can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

- A few people have had hallucinations, but this is rare.
- Occasionally people get skin rashes that are sometimes itchy.
- A few people may find their heartbeat increased.
- A few men, especially men with prostate problems, may have trouble passing water.
- Nausea, vomiting and upset stomach.

Other effects which may occur include:

- Restlessness, having trouble getting to sleep or bad dreams.
- Drowsiness.
- Dry mouth, nose or throat.
- 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 sideeffects 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: <u>www.hpra.ie;</u> Email: <u>medsafety@hpra.ie</u>.

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 the bottle in the outer carton and do not refrigerate.

Keep the medicine tightly closed in the original container.

Keep the product out of the reach and sight of children.

Do not use after the end of the month shown as an expiry date on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further Information

What's in this medicine?

The active ingredients in 5 ml of Benylin 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

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

The Product Licence holder: McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised June 2015. Benylin is a registered trade mark.



Healthcare (Ireland) Ltd.