

## **PACKAGE LEAFLET**

### **Benylin**

#### **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.** *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.

### **1 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.

### **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.

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

**X Do not use this medicine...**

- If you have ever had a **bad reaction** to pseudoephedrine, dextromethorphan, triprolidine, or any of the other ingredients.
- If you suffer from **lung disease**.
- If you have **high blood pressure (hypertension)** 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) or Reversible Inhibitors of Monoamine Oxidase (RIMAs).
- If you are taking *selective serotonin reuptake inhibitors* (SSRIs) (used to treat **depression** and **anxiety** such as fluoxetine, paroxetine and sertraline).
- If you have **diabetes**.
- If you have an **overactive thyroid gland**.
- If you have **glaucoma** (increased pressure in the eye).
- If you have a **phaeochromocytoma** (rare tumour which affects your heart rate and blood pressure).
- If you have **severe acute (sudden) or chronic (long-term) kidney disease or kidney failure**.
- For children under 12 years old.

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 before taking Benylin Dual Action Dry Syrup**

- If you have **liver** or **kidney problems**.
- If you are susceptible to **glaucoma** (increased pressure in the eye).
- 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 difficulty in passing water or need to pass water often (for example, due to prostate problems, or infection or inflammation of the bladder or urinary tract).
- If you have **blocked arteries or veins** (occlusive vascular disease).
- If you have **alcohol dependence**.
- If your child is prone to developing certain **allergic reactions** (e.g. atopic reactions)
- 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 Dual Action 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 experience the following, stop taking the product immediately and contact your doctor:**

- A feverish generalised erythema associated with pustules (see section 4)
  - Sudden abdominal pain or rectal bleeding may occur with Benylin Dual Action Dry Syrup, due to inflammation of the colon (ischemic colitis). If you develop these gastro-intestinal symptoms, stop taking Benylin Phlegm Cough plus Decongestant Syrup, and contact your doctor or seek medical attention immediately. See section 4.
  - Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Benylin Dual Action Dry Syrup immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 “Possible side effects” for symptoms).
  - Sudden severe headaches, nausea, vomiting, confusion, fits, visual disturbances.
- If you are taking any **other medicines**, including:
    - *Sedatives* (drugs used to treat **anxiety and tension**).
    - Certain **drugs for depression** such as norepinephrine-dopamine reuptake inhibitors (NDRIs), which include bupropion
    - *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 the symptoms of **allergic reactions**).
- *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 neurone blockers*, *debrisoquine*, *bretylum* and *betanidine*).
- *Anti-arrhythmic agents* (drugs used to treat **irregular heartbeats** such as *amiodarone*, *propafenone*, *flecainide* and *quinidine*).
- *Anticholinergic drugs* (drugs used to treat **cramps** and **spasms** such as *atropine*)
- *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**.

### **! If you are pregnant or breast-feeding**

- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **! Special warnings about this medicine**

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

### **! Some of the ingredients can cause problems**

- Each 10 ml dose of this medicine contains 5.6 g of sucrose. This should be taken into account in patients with diabetes mellitus.
- This medicine contains 2 g sorbitol in each 10 ml dose. If your doctor has told you that you (or your child) 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. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- This medicine contains 415 mg of alcohol (ethanol) in each 10 ml dose. The amount in each 10 ml dose of this medicine is equivalent to 10 ml beer or 5 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine
- Methyl hydroxybenzoate (E218) may cause allergic reactions such as skin rash; this may happen after a few days.
- The red colouring, Ponceau 4R (E124) in this medicine may cause allergic reactions.
- This medicines contains 8.4mg benzoate salt in each 10ml dose.
- This medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially ‘sodium-free’.

### 3 How to take this medicine

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

- For oral use only.
- Always **shake the bottle** thoroughly before use.
- Do not take more medicine than the label tells you to.
- Do not use to sedate a child
- Do not overfill the spoon.

There is a double-ended spoon in the pack. 

#### **i Adults and Children over 12 years**

Age	Dose
<b>Adults and children aged 12 years and over</b>	Take <b>two large 5 ml spoonfuls</b> every 4 - 6 hours, up to 4 times a day
<ul style="list-style-type: none"> <li>■ Do not take more than 4 doses in 24 hours.</li> <li>■ Leave at least 4 hours between doses.</li> <li>■ If symptoms persist or worsen talk to your doctor or pharmacist.</li> </ul>	

### **! If anyone has too much**

If you take more Benylin Dual Action Dry 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.!

### **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 seek immediate medical help:**

- Stop using Benylin Dual Action Dry Syrup immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include: severe headache with a sudden onset, feeling sick, vomiting, confusion, seizures changes in vision.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) may occur within the first 2 days of treatment with this medicine (See section 2).
- Severe headache, nausea, vomiting, confusion, fits, visual disturbances.

- Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
- Hallucinations, paranoid delusions or fits

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

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

**Other effects which may occur include:**

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

- Headache.

**Common (may affect up to 1 in 10 people)**

- Difficulty sleeping, dizziness, drowsiness or feeling jittery or nervous.
- Dry mouth, nausea, upset stomach or thickened mucus.
- Blurred vision.

**Rare (may affect up to 1 in 1000 people)**

- Confusion, depression or tremors.
- Low blood pressure.
- Unusual movements

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

- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)
- Agitation, irritability, feeling anxious or feelings of extreme happiness.
- Tingling or numbness of the hands or feet (pins and needles).
- High blood pressure.
- Difficulty in breathing or shallow breathing
- Dry throat or nose or nose bleeds

- Stomach pain, diarrhoea or vomiting.
- Decreased appetite.
- Tremors
- Heart attack/reduced blood flow to the heart which can cause discomfort or pain in the chest, neck, back, jaw, shoulders or arms (known as angina).
- Feeling tired.
- Pain when passing water.
- Inflammation of the colon due to insufficient blood supply (ischemic colitis)

### **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](http://www.hpra.ie).

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

**Marketing Authorisation Holder:** JNTL Consumer Health I (Ireland) Ltd. Block 5, High Street, Tallaght, Dublin 24, Ireland

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

**This leaflet was revised**

Benylin is a registered trade mark.