Benylin
Children's Coughs & Colds
5mg/0.625mg per 5ml Syrup
dextromethorphan, triprolidine

■ This medicine is used to help relieve children's dry cough and cold symptoms.
■ This medicine is for use by children aged 6 to 12 years.
■ **Do not use this medicine:**
■ There are some people who should not use this medicine. *To find out if your child is one of them see section 2>*
■ If your child has ever had a **bad reaction** to any of the ingredients. *See section 6>*
■ **Speak to your doctor:**
■ If your child suffers from any of the conditions mentioned in section 2. *See section 2>*
■ If your child is 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 child's symptoms worsen or do not improve after a few days.

1 What the medicine is for
Benylin Children's Coughs & Colds Syrup is a medicine which is used to help relieve the symptoms of colds and dry coughs. The liquid contains dextromethorphan (an antitussive) to help stop coughing and triprolidine (an antihistamine) to help stop sneezing, runny nose and watery eyes.
The medicine is for use in children aged 6 to 12 years.

2 Before giving the medicine to your child
This medicine is suitable for most children but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not give this medicine…
■ If your child has ever had a **bad reaction** to any of the ingredients.
■ If your child is taking, or has taken in the last two weeks, **drugs for depression** known as Monoamine Oxidase Inhibitors (MAOIs).
■ If your child is taking *selective serotonin reuptake inhibitors* (used to treat **depression** and **anxiety**) such as fluoxetine, paroxetine and sertraline).
■ If your child is taking **any other cough and cold medicine.**
■ If your child has serious **breathing difficulties**.
■ If your child is aged under 6 years.
■ This medicine should not be used to sedate a child.

If any of these apply, **get advice from a doctor or pharmacist without using Benylin Children's Coughs & Colds Syrup**.

! Talk to your doctor or pharmacist…
■ If your child suffers from **liver problems**.
■ If your child is 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 been told that your child is a **slow metabolizer of CYP2D6**.

■ Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines such as:
■ *sedatives*, as their effects may be increased if taken with this medicine (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**).
■ *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**).
■ *anti-arrhythmic agents* (drugs used to treat **irregular heartbeats** such as amiodarone, propafenone, quinidine and flecainide).
■ *calcimimetics*, (drugs to treat **secondary hyperparathyroidism**, elevated parathyroid hormone levels such as cinacalcet).
■ *anti-fungals* (terbinafine).
If you are not sure about any of the medicines your child is taking, show the bottle or pack to your pharmacist.
If any of these bullet points apply now or in the past, **talk to a doctor or pharmacist**.

! If you are pregnant or breast-feeding
The following advice is included in case an older child or adult is taking the medicine:
■ 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
If an older child or adult is taking this medicine:
■ This product may cause drowsiness. Do not drive or operate machinery if you are affected. **Avoid alcoholic drink.**
■ Ask a doctor or pharmacist for advice before taking this medicine if you have a history of **drug abuse,** or **have trouble passing water**.

! Some of the ingredients can cause problems
■ This medicine contains maltitol. If you have been told by your doctor that your child has an intolerance to some sugars contact your doctor before giving this medicine.
■ This medicine contains less than 1 mmol sodium (23mg) per 10 ml dose, that is to say essentially 'sodium-free'.
■ This medicine contains methyl hydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

3 How to use this medicine
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
■ There is a double-ended spoon in this pack.

i Children aged under 6 years
Benylin Children's Coughs & Colds Syrup should not be given to children under 6 years old.

i Children aged 6 - 12 years

Age	Dose
Children 6-12 years	Give two 5ml spoonful's every 6 to 8 hours. Do not give more than 8 spoonful's in one day.
■ Maximum daily dose: 40ml ■ Do not give more than 4 doses (eight 5ml spoonful's) in 24 hours. ■ Use only when simple measures have failed to provide adequate relief. ■ Do not give to a child under 12 years of age for more than 5 days without consulting your doctor.	

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

! If you forget to give the medicine
You should only give this medicine as required following the dosage instructions above carefully. If you forget to give a dose, give the next dose when needed. **Do not** give 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 the medicine and seek immediate medical help:
■ Allergic reactions including skin rashes such as hives (which may be severe and include blistering or peeling of the skin) and itching.
■ Swelling of the face, lips mouth, tongue or throat which may cause difficulty in swallowing or breathing.
■ Hallucinations or fits.

If you experience any of the following, stop using this medicine and talk to your doctor:
■ Restlessness or sleep disturbances.
■ A fast or irregular heartbeat, or an increased awareness of the heartbeat (palpitations).
■ Trouble passing water (especially men with prostate problems).

Other effects which may occur include:

Common (may affect up to 1 in 10 people):
■ Headache.
■ Drowsiness.
■ Feeling jittery

■ Blurred vision.
■ Dry mouth, upset stomach, or thickened mucus.

Rare (may affect up to 1 in 1000 people):
■ Confusion, depression or tremors.
■ Dizziness.
■ Low blood pressure.
■ Unusual or uncontrollable movements such as trembling and shaking.

Other affects which may occur but it is not known how often:
■ Difficulty sleeping.
■ Agitation.
■ Pins and needles.
■ Difficulty breathing, shortness of breath.
■ Stomach pain, nausea, diarrhoea or vomiting.
■ Feeling tired.

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 Storing this medicine

Do not store above 25ºC.
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.
Keep this medicine tightly closed in the original container.
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 Children's Coughs and Colds Syrup:
Triprolidine hydrochloride 0.625 mg, Dextromethorphan hydrobromide 5 mg.
Other ingredients are: Maltitol liquid, glycerol, methyl hydroxybenzoate (E218), sodium benzoate (E211), sodium saccharin, flavouring and purified water.

What the medicine looks like
Benylin Children's Coughs & Colds Syrup is a clear colourless syrup available in 125 ml glass bottles.

Marketing Authorisation holder:
McNeil Healthcare (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland.

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

This leaflet was revised July 2018.
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