



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.** Children of different ages need different amounts. 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 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 drugs for depression such as selective serotonin reuptake inhibitors (SSRIs) as fluoxetine, paroxetine and sertraline.
- If your child is taking **any other cough and cold medicine**.
- If your child has ever had a persistent cough 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 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 or kidney problems**.
- If your child is susceptible to **glaucoma** (increased pressure in the eye).
- If your child has difficulty **breathing** (emphysema) or **chronic bronchitis**.
- If your child suffers from a **chronic or persistent cough**, has **asthma**, suffers from **asthma attacks** or where cough is accompanied by **excessive secretions**.
- If you have a history of **drug abuse**.
- If your child has been told by a doctor that they are 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 inhibitor (NDRI)**, which include bupropion and 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 allergies).
- **anti-arrhythmic agents** (drugs used to treat **irregular heart beats** such as amiodarone, propafenone, quinidine and flecainide).
- **calcimimetic**, (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, only use this medicine on the advice of your doctor.

! Special warnings about this medicine

- If an older child or adult is taking the medicine remember that this product may cause drowsiness. Do not drive or operate machinery if you are affected. Avoid alcoholic drink.

! Some of the ingredients can cause problems

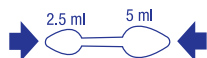
- This medicine contains maltitol. If your child has been told by their doctor that s/he has an intolerance to some sugars contact your doctor before taking this medicine.
- This medicinal product contains 0.92 mg sodium per 5 ml to be taken into consideration by patients on a controlled sodium diet.
- This medicinal product contains methyl hydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

turn over ►

3 How to use this medicine

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

- For oral use only.
- Do not take more than the stated dose shown below.
- There is a double-ended spoon in this pack.



i Children aged under 6 years

Benylin Children's Coughs & Colds Syrup is not recommended for children under 6 years old.

i Children aged 6 - 12 years

Age	Dose
Children 6 – 12 years	Give two 5ml spoonfuls every 6 to 8 hours. Do not give more than 8 spoonfuls in one day.

- Maximum daily dose: 40ml
- Do not give more than 4 doses (eight 5ml spoonfuls) 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 help:

- Allergic reactions including skin rashes (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 and fits.
- Heartbeat increased, or increased awareness of the heartbeat (palpitations).
- Difficulty breathing, shortness of breath.
- Nausea, vomiting, upset stomach.
- Restlessness or sleep disturbances.
- Difficulty in passing water.

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

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

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

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

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

- Difficulty sleeping.
- Agitation.
- Pins and needles.
- Stomach pain or discomfort, diarrhoea or vomiting.
- Fatigue.

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 above 25°C.

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 solution, 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 Concy, 45071 Orleans, Cedex 2, France.

This leaflet was revised December 2016.

Benylin is a registered trade mark.

McNeil
Healthcare (Ireland) Ltd.

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Orleans - Artworks Center

Client	JNJ		
Change request #	CRD 0XXX		
Product	BENYLIN CHILDREN'S COUGH & COLD 125ML IE		
Component #	LN50XX01		
Old component #	F310532		
ATW version	11.0		
Component type	Rolled Leaflet		
Dimensions	160 x 210 mm		
Drawing #	NOTC010		
Safety code type & #	Datamatrix LN50XX01		
Client code	16-0649		
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 355	PMS 355		
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.			