
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS**S2****BENYLIN® ORIGINAL syrup**

Diphenhydramine hydrochloride 12,5 mg and ammonium chloride 125,0 mg per 5 mL of syrup.

Contains sugar: Each 5 mL contains 1 g sucrose and 2,3 mL glucose.

Contains sweetener: Each 5 mL contains 15,5 mg saccharin sodium and 20 mg sodium cyclamate.

Read all of this leaflet carefully because it contains important information for you.

BENYLIN® ORIGINAL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use BENYLIN® ORIGINAL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BENYLIN® ORIGINAL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What BENYLIN® ORIGINAL is and what it is used for.
2. What you need to know before you use BENYLIN® ORIGINAL.
3. How to use BENYLIN® ORIGINAL.
4. Possible side effects.
5. How to store BENYLIN® ORIGINAL.
6. Contents of the pack and other information.

1. What BENYLIN® ORIGINAL is and what it is used for

BENYLIN® ORIGINAL contains an antihistamine (diphenhydramine) and an expectorant (ammonium chloride).

BENYLIN® ORIGINAL is used to relieve cough.

2. What you need to know before you use BENYLIN® ORIGINAL

Do not use BENYLIN® ORIGINAL

- If you are hypersensitive (allergic) to diphenhydramine, ammonium chloride or any of the other ingredients of BENYLIN® ORIGINAL (see **What BENYLIN® ORIGINAL contains**).
- If you are taking or have taken within the last 2 weeks, monoamine oxidase inhibitors (MAOI) for depression.
- During an acute asthma attack.
- If you have liver or kidney disease.

BENYLIN® ORIGINAL should not be used in children below 6 years of age.

Warnings and precautions

Take special care with BENYLIN® ORIGINAL

- BENYLIN® ORIGINAL may lead to drowsiness and affect concentration. Do not use it with another medicine which also causes drowsiness.
- If you suffer from and respiratory diseases such emphysema (lungs are enlarged and damaged), persistent inflammation of the bronchi or acute or persistent bronchial as asthma, water on the lungs or blocked airway disease.
- If you have a persistent cough accompanied by excessive, mucus (phlegm) unless you are advised to use BENYLIN® ORIGINAL under the supervision of your doctor.
- If you have liver disease or diseases of the heart and blood vessels.
- If you have glaucoma (increased pressure in your eye), difficulty urinating, an enlarged prostate gland.

Avoid alcohol when you take BENYLIN® ORIGINAL.

If your symptoms persist or worsen, or if new symptoms occur, stop using BENYLIN® ORIGINAL and consult your doctor.

Children and adolescents

BENYLIN® ORIGINAL should not be used in children below 6 years of age (see **Do not use BENYLIN® ORIGINAL**).

Other medicines and BENYLIN® ORIGINAL

Always tell your health care provider if you are taking or giving your child any other medicine.

(This includes complementary or traditional medicines.)

It is especially important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Atropine, tricyclic anti-depressants and anti-depressants known as monoamine oxidase inhibitors (MAOI) or within 14 days of stopping treatment with MAOIs,
- Hypnotics, centrally acting muscle relaxants, or other medicines that work on the central nervous system, such as, alcohol, sleeping tablets, painkillers, tranquillisers, anti- psychotic medicines or anaesthetics,
- Aminoglycoside, which is an antibiotic, Other medicines which also contain diphenhydramine (including topical preparations) ammonium chloride.

BENYLIN® ORIGINAL can affect the outcome of skin tests that are performed.

If you are not sure about any of the medicines you are using or taking, show the bottle or pack to your pharmacist or health care professional for advice.

BENYLIN® ORIGINAL with food, drink and alcohol

Do not drink any alcohol while you are using BENYLIN® ORIGINAL.

Pregnancy, breastfeeding and fertility

Do not use BENYLIN® ORIGINAL if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BENYLIN® ORIGINAL.

Driving and using machines

BENYLIN® ORIGINAL may cause side effects, such as drowsiness, dizziness, incoordination or blurred vision. Do not drive a vehicle, operate machinery or climb dangerous heights if you are affected by BENYLIN® ORIGINAL as weakened decision-making could lead to accidents.

BENYLIN® ORIGINAL contains sucrose, glucose and sodium benzoate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BENYLIN® ORIGINAL.

BENYLIN® ORIGINAL contains sugar (sucrose and glucose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

BENYLIN® ORIGINAL contains sodium benzoate which may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

BENYLIN® ORIGINAL contains alcohol

BENYLIN® ORIGINAL contains alcohol. It contains 0,258 mL of alcohol (ethanol) in each 5 mL.

The small amount of alcohol in BENYLIN® ORIGINAL will not have any noticeable effects.

3. How to use BENYLIN® ORIGINAL

Do not share medicines prescribed for you with any other person.

For oral use only.

DO NOT USE MORE THAN THE RECOMMENDED DOSE.

Adults and children over 12 years: One to two medicine measures (5 mL – 10 mL) every 4 hours.

Children 6 to 12 years: A half to one medicine measure (2,5 mL – 5 mL) every 4 hours.

If your symptoms persist or worsen, or if new symptoms occur, stop using BENYLIN® ORIGINAL and speak to your doctor.

Children under 6 years of age:

Do not give BENYLIN® ORIGINAL to children younger than 6 years.

BENYLIN® ORIGINAL can be taken with or without food.

If you have the impression that the effect of BENYLIN® ORIGINAL is too strong or too weak, tell your doctor or pharmacist.

If you use more BENYLIN® ORIGINAL than you should

Signs of too much BENYLIN® ORIGINAL can include fits or tremors, hallucinations, coma, low blood pressure, abnormal heart rate or difficulty in breathing.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of BENYLIN® ORIGINAL

You should only give this medicine as required and by following the dosage instructions above carefully. If you forget to take/give a dose, take/give the next dose when needed provided that the last dose was at least 4 hours ago. Do not take/give a double dose to make up for the forgotten individual doses.

4. Possible side effects

BENYLIN® ORIGINAL can have side effects.

Not all side effects reported for BENYLIN® ORIGINAL are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while taking BENYLIN® ORIGINAL, please consult your health care provider for advice.

If any of the following happens, stop using BENYLIN® ORIGINAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A sudden, life-threatening allergic reaction with swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty breathing and swallowing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BENYLIN® ORIGINAL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent:

- Signs of recurrent infections, such as fever or sore throat.
- Unexplained bleeding, pin-point bleeds or bruising of your skin.
- Convulsions (fits).
- Changes in the way your heart beats (such as beating faster or skipping a beat).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently:

- The most common side effects are sedation (varying from slight drowsiness to deep sleep), lassitude (physical or mental weariness), dizziness, or incoordination, headache, dry mouth and thickened mucus secretions from the lungs.

Less frequent:

- Confusion, irritability, hallucinations, nervousness, agitation, lack of sleep, blurred vision, ringing in the ears, chest discomfort or tightness, nausea, vomiting, diarrhoea, constipation, difficulty in urination or a sense of weakness, stomach pain, application site reaction (including a burning sensation of your mouth; dryness, pain or blistering of your lip/s; inflammation of your tongue; inflammation, ulceration or redness of your mouth; blistering of your throat).
- Low blood pressure.
- Dry throat or nose.
- Indigestion.
- Sensitivity of your skin to light (photosensitivity), muscle weakness or general weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BENYLIN® ORIGINAL.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

5. How to store BENYLIN® ORIGINAL

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in a cool place.
- Keep the bottle sealed.

- Keep the bottle in the outer carton.
- Do not use your medicine after the date shown as an expiry date on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BENYLIN® ORIGINAL contains

Each 5 mL of syrup contains the following active substances:

Diphenhydramine hydrochloride 12,5 mg and ammonium chloride 125,0 mg with ethanol 97 % v/v 5,0 % v/v and sodium benzoate 0,2 % m/v as preservative.

The other ingredients are caramel (colourant), citric acid, glucose, glycerine, H & R special flavour (flavourant), menthol (flavourant), ponceau red (colourant), raspberry flavour (flavourant), saccharin sodium, sodium benzoate, sodium citrate, sodium cyclamate, sucrose and purified water.

BENYLIN® ORIGINAL contains alcohol.

What BENYLIN® ORIGINAL looks like and contents of the pack

A clear, dark brown syrup having a raspberry odour and taste.

Round, amber glass bottles containing 100 mL or 200 mL of syrup with a clearly graded plastic measuring cup.

Holder of certificate of registration

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