

BENYLIN® DRY COUGH
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

BENYLIN® Dry Cough syrup

Dextromethorphan hydrobromide

Preservative: Sodium benzoate 0,5 % *m/v*.

Contains sweetener: Each 5 mL contains 20 mg sodium cyclamate and 1,5 mg saccharin
sodium.

Contains sugar alcohol: Each 5 mL contains 2,5 g sorbitol.

Sugar free.

Alcohol free.

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

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

Nevertheless, you still need to take BENYLIN® Dry Cough carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve (after 7 days).

What is in this leaflet

1. What BENYLIN® Dry Cough is and what it is used for.
2. What you need to know before you take BENYLIN® Dry Cough.
3. How to take BENYLIN® Dry Cough.
4. Possible side effects.
5. How to store BENYLIN® Dry Cough.

6. Contents of the pack and other information.

1. What BENYLIN® Dry Cough is and what it is used for

BENYLIN® Dry Cough contains dextromethorphan hydrobromide which is a centrally acting cough suppressant. It is a medicine which is used to help relieve dry, irritating coughs.

2. What you need to know before you take BENYLIN® Dry Cough

Do not take BENYLIN® Dry Cough:

- If you are hypersensitive (allergic) to dextromethorphan or any of the other ingredients of BENYLIN® Dry Cough (see **6. What BENYLIN® Dry Cough contains**).
- If you are taking, or you have taken in the last two weeks, medicines to treat depression known as monoamine oxidase inhibitor (MAOIs).
- If you suffer from asthma.
- If you have any liver problems.

BENYLIN® Dry Cough should not be given to children under 5 years of age.

Warnings and precautions

Take special care with BENYLIN® Dry Cough:

- If you have a persistent cough, such as occurs with asthma, smoking, emphysema or chronic bronchitis;
- if you have a cough that produces a lot of mucus (phlegm)
- if you have been told by your doctor that you are a slow metaboliser of CYP2D6.

BENYLIN® Dry Cough can lead to dependence. Caution is advised with BENYLIN® Dry Cough if you, or your child, are an adolescent, if you are a young adult, or you have a history of drug/substance abuse.

Other medicines and BENYLIN® Dry Cough

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using:

- Monoamine oxidase inhibitors (MAOIs) (used to treat depression) (see **Do not take BENYLIN® Dry Cough** above);
- central nervous system depressants (used as sedatives/tranquilisers, or to treat anxiety, stress or sleep disorders);
- fluoxetine, paroxetine, sertraline, bupropion, selective serotonin reuptake inhibitors (SSRIs) (used to treat depression);
- quinidine, amiodarone, flecainide, propafenone (used to treat an abnormal heartbeat);
- terbinafine, isavuconazole (used to treat fungal infections);
- methadone (used to treat pain and for the detoxification or maintenance of addiction);
- cinacalcet (used to treat high levels of calcium in your blood if you have an overactive thyroid);
- haloperidol, thioridazine (used to treat schizophrenia);
- perphenazine (used to treat psychosis or hallucinations).

BENYLIN® Dry Cough with food, drink and alcohol

See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, 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® Dry Cough.

Safety of BENYLIN® Dry Cough during pregnancy and lactation has not been established. Do not use BENYLIN® Dry Cough if you are pregnant or breastfeeding.

Driving and using machines

BENYLIN® Dry Cough can cause side effects, such as drowsiness and dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BENYLIN® Dry Cough affects you.

BENYLIN® Dry Cough contains sodium benzoate:

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take BENYLIN® Dry Cough

For oral use only.

Do not share medicines with any other person.

Shake the bottle before use.

The usual dose is:

Adults: One medicine measure (5 mL) every four hours, or two medicine measures (10 mL) every six to eight hours.

Children 5 to 12 years: Half to one medicine measure (2,5 mL – 5 mL) every six to eight hours.

BENYLIN® Dry Cough is not recommended for use in children below 5 years of age.

Do not exceed the recommended dosage. Always take BENYLIN® Dry Cough exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

If you take more BENYLIN® Dry Cough than you should

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

Take this leaflet and the rest of the remaining BENYLIN® Dry Cough with you so the doctor will know what you have taken.

If you forget to take BENYLIN® Dry Cough

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BENYLIN® Dry Cough can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- 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® Dry Cough. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- difficulty sleeping (insomnia);
- dizziness, drowsiness, restlessness (uncontrolled movements, rapid talking, tapping of hands or feet);
- stomach disturbances, pain of your stomach area, diarrhoea, nausea (feeling sick), vomiting (being sick);
- hives (allergic skin reaction).

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® Dry Cough.

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

5. How to store BENYLIN® Dry Cough

- Store at or below 25 °C.
- Store in a cool place.
- Keep tightly closed.
- Keep the container in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/label/ carton.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BENYLIN® Dry Cough contains

Each 5 mL syrup contains:

Dextromethorphan hydrobromide	15 mg
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The other ingredients are citric acid hydrous (E330), D&C YELLOW NO. 10, FD&C BLUE NO. 1 (E133), FD&C RED NO. 40 (E129), glycerine (E422), menthol (flavourant), propylene glycol (E1520), raspberry flavour, saccharin sodium (E954), sodium benzoate (E211), sodium carboxymethylcellulose (E466), sodium citrate hydrous (E331), sodium cyclamate (E952), sorbitol (E420), purified water.

What BENYLIN® Dry Cough looks like and contents of the pack

Dark brown syrup with a faint odour of menthol and raspberries.

Amber glass bottles containing 100 mL and 200 mL, with a plastic measuring cup.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

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7945

South Africa

This leaflet was last revised in

21 December 2021.

Registration number

Z/10.1/5