

**BENYLIN® PAEDIATRIC****PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S2****BENYLIN® PAEDIATRIC syrup****Diphenhydramine hydrochloride****Contains sugar (Each 5 mL contains 1,5 g sucrose and 3,5 g glucose).****Contains sweetener (Each 5 mL contains 15 mg saccharin sodium).****Read all of this leaflet carefully because it contains important information for you.**

- BENYLIN® PAEDIATRIC is available without a doctor's prescription, for your child to treat a mild illness. Nevertheless, you still need to give BENYLIN® PAEDIATRIC carefully to get the best results from it.
- Do not share BENYLIN® PAEDIATRIC with any other person.
- 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 child's symptoms worsen or do not improve in a few days.

**What is in this leaflet**

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

**1. What BENYLIN® PAEDIATRIC is and what it is used for**

BENYLIN® PAEDIATRIC contains diphenhydramine hydrochloride which belongs to a group of medicines known as antihistamines. BENYLIN® PAEDIATRIC is a medicine used to relieve the symptoms of cough and congestion. It also helps relieve runny nose and sneezing associated with hay fever and other allergies. The medicine is for use in children aged 6 to 12 years.

## 2. What you need to know before you take BENYLIN® PAEDIATRIC

### Do not give BENYLIN® PAEDIATRIC to your child

- If your child is hypersensitive (allergic) to diphenhydramine or any of the other ingredients of BENYLIN® PAEDIATRIC (see **What BENYLIN® PAEDIATRIC contains**).
- If your child is taking, or has taken in the last two weeks, medicines for depression known as monoamine oxidase inhibitors (MAOIs).
- If your child is having an asthmatic attack.
- If your child has liver or kidney problems.
- If your child is younger than 6 years.
- If your child has a persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a doctor.

### Warnings and precautions

Take special care with BENYLIN® PAEDIATRIC:

- If your child suffers from fits (seizures).
- If your child suffers from or has had closed angle glaucoma (increased pressure in the eye).
- If your child has difficulty passing water (urinary retention).
- If your child has liver or heart problems.

BENYLIN® PAEDIATRIC contains alcohol and can make some people feel drowsy, dizzy or

cause blurred vision. Make sure that your child is not affected if he or she is going to do anything where they need to be alert. Be especially careful if the child is taking another medicine which may also cause drowsiness.

### **Other medicines and BENYLIN® PAEDIATRIC**

Always tell your health care provider if your child is taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if your child is currently using:

- atropine (used to treat some eye conditions and occasionally bowel conditions);
- tricyclic antidepressants (medicines used to treat mood disorders);
- monoamine oxidase inhibitors (MAOIs) (used to treat depression);
- antibiotic medicines (used to treat bacterial infections);
- barbiturates or hypnotics (used to treat sleeping disorders);
- opioid analgesics (medicines used to relieve pain);
- tranquilisers or sedatives (medicine used to relax muscles or decrease anxiety).

### **BENYLIN® PAEDIATRIC with food, drink and alcohol**

No alcohol-containing products should be consumed during treatment with BENYLIN® PAEDIATRIC.

### **Pregnancy, breastfeeding and fertility**

Safety and efficacy of BENYLIN® PAEDIATRIC during pregnancy and lactation have not been established.

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® PAEDIATRIC.

### **Driving and using machines**

BENYLIN® PAEDIATRIC can cause side effects, such as drowsiness, dizziness or blurred vision. Make sure that your child is not affected if he or she is going to do anything where they need to be alert. Be especially careful if your child is taking another medicine which may also cause drowsiness.

If you are an adult taking BENYLIN® PAEDIATRIC, do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how BENYLIN® PAEDIATRIC affects you.

### **BENYLIN® PAEDIATRIC contains sucrose and glucose**

If you have been told by your doctor that your child has an intolerance to some sugars, consult your doctor before giving BENYLIN® PAEDIATRIC to your child.

### **BENYLIN® PAEDIATRIC 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® PAEDIATRIC**

Do not share medicines with any other person.

For oral use only.

Shake the bottle before use.

*For children 6 to 12 years*

The usual dose is two 5 mL medicine measures (10mL) every 3 hours.

Do not give more than 4 doses in 24 hours.

#### *Children under 6 years*

Do not give to children under 6 years old.

BENYLIN® PAEDIATRIC can be taken with or without food.

Do not exceed the recommended dosage.

Always give BENYLIN® PAEDIATRIC 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® PAEDIATRIC is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more BENYLIN® PAEDIATRIC 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® PAEDIATRIC with you so the doctor will know what you have given to your child.

#### **If you forget to take BENYLIN® PAEDIATRIC**

If you forget to give BENYLIN® PAEDIATRIC to your child, give the next dose when needed provided that the last dose was at least 6 hours ago. Do not give a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

BENYLIN® PAEDIATRIC can have side effects.

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

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

- swelling of your child's hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to BENYLIN® PAEDIATRIC. Your child 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:**

- bleeding or bruising more easily than normal;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- fits (seizures);
- changes in the way your heart beats (beating faster or skipping beats);
- difficulty urinating, pain when urinating, inability to empty your bladder completely.

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

Tell your doctor if you notice any of the following:

*Side effect occurring frequently:*

- sedation (depressed consciousness).

*Side effects occurring less frequently:*

- pain in the upper, middle region of your stomach;
- lack/loss of appetite (anorexia), increased appetite;
- unrealistic feeling of well-being;
- being confused;
- seeing or hearing things that does not exist;
- headache or dizziness;
- feeling nervous, irritated or agitated;
- abnormal coordination;
- difficulty falling or staying asleep (insomnia);
- tingling or numbness of your hands and feet (pins and needles);
- drowsiness or sleepiness;
- tremors (involuntary trembling or shaking of your hands and feet);
- blurred vision;
- ringing in your ears;
- low blood pressure;
- tightness of your chest, dry throat, nasal dryness;
- nausea (feeling sick), vomiting (being sick), diarrhoea, constipation, dry mouth;
- muscle weakness;
- abnormal physical weakness or lack of energy.

*Side effects occurring with unknown frequency:*

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration).

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® PAEDIATRIC.

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

### 5. How to store BENYLIN® PAEDIATRIC

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

Each 5 mL contains:

Diphenhydramine hydrochloride      7 mg

The other ingredients are L-menthol, citric acid (E330), D & C Red No.10 (CI 14720) (colourant), ethanol 95 %, glucose, glycerine (E422), purified water, raspberry flavour (flavourant), saccharin sodium (E954), sodium benzoate (E211), sodium citrate (E331), sugar (sucrose).

Preservative: sodium benzoate                      0, 5 % *m/v*

Contains alcohol: Ethanol 95 %:                      5 % *v/v*

### **What BENYLIN® PAEDIATRIC looks like and contents of the pack**

A clear, bright red syrup having a raspberry odour and taste.

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

### **Holder of certificate of registration**

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