SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Diphenhydramine hydrochloride 7 mg/ 5 ml syrup

Benylin paediatric syrup

2. Qualitative and quantitative composition

Each 5 ml of syrup contains 7.0 mg diphenhydramine hydrochloride.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup

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

4. Clinical particulars

4.1 Therapeutic indications

Diphenhydramine is indicated for the temporary relief of:
• Cough
• Common cold symptoms of runny nose and sneezing
• Hay fever and other upper respiratory allergy symptoms of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes

Diphenhydramine is indicated for the:
• Treatment of allergic dermatoses such as urticaria, food allergy and pruritus.

4.2 Posology and method of administration

Posology

The following is the recommended dosages to be administered to the various age groups.

Do not exceed the maximum dose.

Cough:

Children 2- 6 years

One medicine measure (5 ml) every 4 hours. The total daily recommended dose is 42 mg (30 ml or six medicine measures) in divided doses.

Children 6 - 12 years:

Two medicine measures (10 ml) every 4 hours. The total daily recommended dose is 84 mg (60 ml or twelve medicine measures) in divided doses.

Children over 12 years:

Up to four medicine measures (20 ml) every 4 hours. The total daily recommended dose is 168 mg (60 ml or twelve medicine measures) in divided doses.

Hay fever/Allergy/Common cold

Children 2- 6 years

One medicine measure (5 ml) every 4 - 6 hours. The total daily recommended dose is 37,5 mg (25 ml or five medicine measures) in divided doses.

Children 6 - to 12 years:

Two medicine measures (10 ml) every 4 - 6 hours. The total daily recommended dose is 150 mg (105 ml or twenty one medicine measures) in divided doses.

Children over 12 years:

Up to four medicine measures (20 ml) every 4 - 6 hours. The total daily recommended dose is 300 mg in divided doses.

4.3 Contraindications

Hypersensitivity to diphenhydramine or to any of the formulation excipients.

This medicine is contraindicated during acute asthmatic attacks and in patients with impaired hepatic or renal functions.

Not for children under the age of 2 years.

4.4 Special warnings and precautions for use

Warnings

This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

Do not use with any other product containing diphenhydramine, even one used on skin. Patients should not use this product for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a medical practitioner.

Precautions for use

Use with care in conditions such as angle-closure glaucoma, urinary retention, prostatic hyperplasia, or pyloroduodenal obstruction.

Use with caution in epileptic patients as occasional convulsions have been reported. Dosage reduction may be necessary in those patient with renal and hepatic impairment. Patients with acute or chronic bronchial asthma.

Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, and tranquilizers. Therefore avoid alcoholic beverages and consult a healthcare professional prior to taking together with central nervous system depressants.

When coughs are either persistent or chronic as in asthma or when there is excessive secretions, avoid use of diphenhydramine containing products.

4.5 Interaction with other medicinal products and other forms of interaction

Central depressants: Diphenhydramine may enhance the sedative effects of central nervous system depressants, including alcohol, sedatives, and tranquilizers.

Antimuscuranic medicines: Diphenhydramine may have an additive effect with medicines such as atropine, tricyclic antidepressants, and mono-amine oxidase inhibitors.

Antibacterials: Diphenhydramine may mask the damage caused by ototoxic medicines such as aminoglycosides

Cough and Cold preparations: Avoid concurrent use as other preparation could have similar acting components which will result is a potentiation of the effect of both products.

Laboratory tests: Diphenhydramine may suppress cutaneous histamine response to allergen.

4.6 Fertility, pregnancy, and lactation

There are no adequate and well-controlled studies of diphenhydramine in pregnant or breast-feeding women.

Pregnancy:

Several large studies have failed to find any strong associations between foetal abnormalities and antihistamines taken during pregnancy

Lactation:

Diphenhydramine crosses the placenta and is excreted into breast milk, but levels have not been reported

Fertility

There is insufficient information to determine whether diphenhydramine HCl has the potential to impair fertility in animals. A reproductive risk to humans has not been established.

4.7 Effects on ability to drive and use machines

Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable effects
Side Effects

Nervous system disorders:

Frequent: depression varying from slight drowsiness to deep sleep including lassitude, dizziness, and incoordination, headache and antimuscarinic effects, such as dry mouth and thickened respiratory-tract secretions

Frequency unknown: Paradoxical stimulation may occur occasionally especially with high doses and in children.
These effects may diminish after a few days of treatment.

Eye disorders:

Frequent: Blurred vision,

Gastrointestinal disorders:

Frequent: Constipation and increased gastric reflux.

Musculoskeletal, connective tissue and bone disorders:

Frequent: Psychomotor impairment

Renal and urinary disorders:

Frequent: Urinary difficulty or retention

The following post marketing side effects have been reported for diphenhydramine:

Clinical studies or epidemiology studies

Psychiatric disorders:

Less frequent: Confusional state, irritability, and nervousness.

Frequency unknown: Hallucination

Nervous system disorders:

Frequent: Sedation

Less frequent: Agitation and insomnia,

Frequency unknown: Coordination abnormalities, convulsion, headache, paraesthesia and tremor

Eye disorders:

Frequency unknown: blurred vision

Ear and labyrinth disorders:

Frequency unknown: Tinnitus

Cardiac disorders:

Frequency unknown: Hypotension, palpitations, and tachycardia

Respiratory, thoracic, and mediastinal disorders:

Frequent: Dry throat

Less frequent: Chest discomfort and nasal dryness

Gastrointestinal disorders:

Frequency unknown: Constipation, diarrhoea, dyspepsia, nausea, and vomiting

Skin and subcutaneous tissue disorders:

Less frequent: Rash

Frequency unknown: Pruritus and urticaria

Renal and urinary disorders:

Frequency unknown: Urinary retention

Spontaneous reports:

Psychiatric disorders:

Less frequent: Confusional state, irritability, hallucination, and nervousness

Nervous system disorders:

Less frequent: Agitation, insomnia, convulsion, dizziness, headache, insomnia, paraesthesia, sedation, somnolence, and tremor

Eye disorders:

Frequency unknown: Blurred vision

Ear and labyrinth disorders:

Frequency unknown: Tinnitus

Cardiac disorders:

Frequency unknown: Hypotension, palpitations, and tachycardia

Respiratory, thoracic, and mediastinal disorders:

Less frequent: Chest discomfort, dry throat and, nasal dryness

Gastrointestinal disorders:

Less frequent: Constipation, diarrhoea, dyspepsia, dry mouth, nausea, and vomiting

Skin and subcutaneous tissue disorders:

Less frequent: Rash, pruritus and urticaria

Renal and urinary disorders:

Less frequent: Urinary retention

General disorders and administrative site conditions:

Less frequent: Asthenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose

Signs and symptoms of overdosage with sedating antihistamines are associated with antimuscarinic, extrapyramidal, and central nervous system effects (CNS).
CNS stimulations are more likely in children or the elderly and causes ataxia, excitement, tremors, psychoses, hallucinations, and convulsions; hyperpyrexia may also occur followed by deepening coma and cardiorespiratory collapse. However, CNS depression signs are more common.

Mild to moderate symptoms are:

Somnolence, anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, mild hypertension, nausea and vomiting are common after overdose. Agitation, confusion, and hallucinations may develop with moderate poisoning.

Severe symptoms:

Effects may include delirium, psychosis, seizures, coma, convulsions, hypotension, QRS widening, and ventricular dysrhythmias, including torsade's de pointe, but are generally reported in adults after large ingestions. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma, or seizures. Death may occur as a result of respiratory failure or circulatory collapse.

Further treatment is symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological Classification: 22.2.5 Cough and cold preparations - Combination products (antitussives and expectorants)

5.2 Pharmacokinetic properties

Absorption

No available data.

Distribution

Diphenhydramine is highly bound to plasma proteins.

Metabolism

Metabolism is extensive.

Elimination

Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged molecule. The elimination half-life has been reported to range from 2,4 to 9,3 hours.

5.3 Preclinical safety data

No available data.

6. Pharmaceutical particulars

6.1 List of excipients

Carmoisine

Citric acid

Glucose

Glycerol

Menthol

Raspberry flavour

Saccharin

Sodium citrate

Alcohol

Sodium benzoate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25ºC. Keep container tightly closed. Keep out of reach of children.

6.5 Nature and contents of container

Amber glass bottle having a 100 ml capacity and closed with a lined white polypropylene cap in a single carton.

6.6 Special precautions for disposal and other handling

The treatment procedure should be fully explained and completely understood by the patient.

7. APPLICANT

Johnson & Johnson (Pty) Ltd.

241 Main road, Retreat
7945, Cape town, South Africa

8. MANUFACTURER

Johnson & Johnson (Pty) Ltd.
241 Main road, Retreat
7945, Cape town, South Africa

9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/22.2.5/6372

Zimbabwe category for distribution: Pharmacy Medicines (P.)

10. DATE OF REVISION OF THE TEXT

May 2023