

Module 1.3.2 Patient Information Leaflet (PIL) – Approved

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

DIPHAL EXPECTORANT Solution

14 mg Diphenhydramine hydrochloride and 136 mg Ammonium chloride per 5 mL

Contains sugar (sucrose) 1 300 mg per 5 mL

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

DIPHAL EXPECTORANT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DIPHAL EXPECTORANT carefully to get the best results from it.

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

What is in this leaflet

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

1. What DIPHAL EXPECTORANT is and what it is used for

DIPHAL EXPECTORANT belongs to a group of medicines called antitussives and expectorants and is used for the relief of cough.

2. What you need to know before you take DIPHAL EXPECTORANT

Do not take DIPHAL EXPECTORANT:

- if you are allergic to diphenhydramine hydrochloride or ammonium chloride or any of the other ingredients of DIPHAL EXPECTORANT as listed above.
- if you suffer from liver or kidney disease
- if you have asthma or **any progressive lung diseases (COPD)** including emphysema (destructive lung condition with loss of elasticity), chronic bronchitis (inflammation of the air passages of the lungs) and some forms of bronchiectasis (chronic inflammation and infection of the bronchi walls).
- if you use a certain type of anti-depressant called monoamine oxidase inhibitors including linezolid or if you have used it in the past 14 days.

DIPHAL EXPECTORANT should not be used in children under the age of 6 years.

Warnings and precautions

Take special care with DIPHAL EXPECTORANT:

- if you suffer from heart problems, high blood pressure, toxemia of pregnancy (serious metabolic abnormalities during pregnancy associated with increased blood pressure), cardiovascular disease, glaucoma (eye disease), enlargement of the prostate or if you have difficulty in urinating.
- elderly patients are most susceptible to the central nervous system depressant and hypotensive effects.
- the positive results of skin allergy tests may be suppressed.

- with patients taking DIPHAL EXPECTORANT in conjunction with nervous system depressants such as alcohol, barbiturates, hypnotics, narcotics analgesic sedatives and tranquillisers and anticholinergic medicines and tricyclic antidepressants as their effects may be enhanced by diphenhydramine in DIPHAL EXPECTORANT.
- Monoamine-oxidase inhibitors including linezolid may enhance the anticholinergic effects of diphenhydramine hydrochloride.
- The warning signs of damage caused by ototoxic medicines (such as aminoglycoside antibiotics) may be masked by diphenhydramine hydrochloride.
- Do not take DIPHAL EXPECTORANT for a persistent cough which occurs with smoking, asthma or emphysema.

Children

- with administering DIPHAL EXPECTORANT to children as it may cause the children to experience paradoxical (opposite effect) hyperexcitability (tendency to be easily and excessively excited), nervousness, irritability or sleeplessness.
- Do not give DIPHAL EXPECTORANT to children under the age of 6 years old because the safety has not been established.

Other medicines and DIPHAL EXPECTORANT

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

Extreme caution should be exercised with patients taking DIPHAL EXPECTORANT together with medicines such as alcohol, tranquilisers, sleeping tablets, pain killers and certain types of anti-depressants as their effects may be enhanced by the diphenhydramine in DIPHAL EXPECTORANT.

A certain type of anti-depressant medicine called monoamine-oxidase inhibitors including linezolid, may enhance the anticholinergic effects of diphenhydramine hydrochloride. The

warning signs of damage caused by medicines that are toxic to the ears (such as aminoglycoside antibiotics) may be masked by diphenhydramine hydrochloride.

DIPHAL EXPECTORANT with food and drink

You can take DIPHAL EXPECTORANT with or without food.

Do not drink alcohol while you are taking DIPHAL EXPECTORANT.

Pregnancy and breastfeeding

Safety in pregnancy and lactation has 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 this medicine.

Driving and using machines

DIPHAL EXPECTORANT may cause drowsiness and impaired concentration. Do not drive a vehicle, operate machinery or climb dangerous heights if you are affected by DIPHAL EXPECTORANT as weakened decision-making could lead to accidents.

DIPHAL EXPECTORANT contains sugar

If you have been told that you have an intolerance to some sugars, contact your doctor before taking DIPHAL EXPECTORANT.

DIPHAL EXPECTORANT contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

DIPHAL EXPECTORANT contains very small amounts of sodium, that is to say it is essentially 'sodium-free'.

DIPHAL EXPECTORANT contains a small amount of propylene glycol and may have an effect on you if you have liver or kidney disease, in which case, do not take DIPHAL EXPECTORANT unless recommended by your doctor. Your doctor may carry out extra checks while you are taking DIPHAL EXPECTORANT.

3. How to take DIPHAL EXPECTORANT

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

Always take DIPHAL EXPECTORANT exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Shake the bottle before use.

Do not exceed a maximum of four doses per day.

The usual dose is:

Adults: One to two medicine measures (5 to 10 mL) every three to four hours.

Children 6 to 12 years: Half to one medicine measure (2,5 to 5 mL) every four hours (see your doctor after two weeks if there is no improvement).

DIPHAL EXPECTORANT should not be used in children under the age of 6 years.

If you have the impression that the effect of DIPHAL EXPECTORANT is too strong or too weak, talk to your doctor or pharmacist.

If you take more DIPHAL EXPECTORANT than you should

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

Overdosage may be fatal, especially in children. Symptoms are central nervous system stimulation, increased heart rate, excitement, drowsiness, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and abnormal high body temperature and death may occur from respiratory failure.

Take this leaflet or the bottle with medicine with you so your doctor will know what you have taken.

If you forget to take DIPHAL EXPECTORANT

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

4. Possible side effects

DIPHAL EXPECTORANT can have side effects.

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

If any of the following happens, stop using DIPHAL EXPECTORANT 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 DIPHAL EXPECTORANT. 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 or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online

under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DIPHAL EXPECTORANT.

5. How to store DIPHAL EXPECTORANT

Store all medicines out of reach of children.

- Store in a cool place, at or below 25 °C. Protect from light.
- Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIPHAL EXPECTORANT contains

- The active substances are (per 5 mL):
Diphenhydramine hydrochloride 14 mg
Ammonium chloride 136 mg
- DIPHAL EXPECTORANT contains a preservative (Nipastat).
- DIPHAL EXPECTORANT contains sugar (sucrose).
- The other ingredients are: caramel 4800 (flavour), essence of raspberry No. 1 (flavour), Invert syrup, menthol (flavour), propylene glycol, purified water, sodium citrate.

What DIPHAL EXPECTORANT looks like and contents of the pack

A clear brown syrupy liquid.

Packed in 100 mL round amber PVC bottles with white LDPE screw on or snap-on caps, or
200 mL round amber PVC bottles with white LDPE snap-on caps.

Holder of Certificate of Registration

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Access to the corresponding Professional Information (PI)

An online copy of the PI is available at

<https://unimedhealthcare.co.za/proffessional-information/>