SCHEDULING STATUS

S2

RELIEF-COFF EXPECTORANT, solution

Diphenhydramine hydrochloride

Ammonium chloride

Sodium citrate

Contains sweetener as saccharin sodium 7,50 mg per 5 ml

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

RELIEF-COFF EXPECTORANT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use RELIEF-COFF EXPECTORANT carefully to get the best results from it.

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

What is in this leaflet

1 What RELIEF-COFF EXPECTORANT is and what it is used for

2. What you need to know before you take RELIEF-COFF EXPECTORANT

3. How to take RELIEF-COFF EXPECTORANT

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1. What RELIEF-COFF EXPECTORANT is and what it is used for

RELIEF-COFF EXPECTORANT contains diphenhydramine hydrochloride, ammonium chloride and sodium citrate. It is used to help relieve coughing.

The medicine is for use in adults and children aged 6 years and older.

2. What you need to know before you take RELIEF-COFF EXPECTORANT

Do not take RELIEF-COFF EXPECTORANT:

- If you are hypersensitive (allergic) to diphenhydramine hydrochloride, ammonium chloride, sodium citrate or any of the other ingredients of RELIEF-COFF EXPECTORANT (listed in section 6).
- If you suffer from liver or kidney disease.
- If you suffer from asthma and COPD (chronic obstructive pulmonary disease).
- If you are pregnant or breastfeeding.
- If you have epilepsy.

Warnings and precautions

Special care should be taken with RELIEF-COFF EXPECTORANT:

- When you drive a vehicle or be in charge of machinery. The use of RELIEF-COFF EXPECTORANT can lead to drowsiness and impaired concentration, which is aggravated by the simultaneous intake of alcohol. It can impair decision making which could lead to accidents.
- If you suffer from heart problems, high blood pressure, water retention, heart disease, glaucoma (eye disease), enlargement of the prostate or if you have difficulty in urinating.
- If you are elderly as you could be more susceptible to the central nervous system depressant (slows down activities in your brain and produces feelings of drowsiness, confusion, or

disorientation) and lower your blood pressure.

- Do not take more RELIEF-COFF EXPECTORANT than you should as large doses can make you feel sick, cause you to vomit, feel thirsty, sleepy and confused.

Children

RELIEF-COFF EXPECTORANT should not be used in children under the age of 6 years.

Other medicines and RELIEF-COFF EXPECTORANT

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

Extreme caution should be exercised with the following:

- If an allergen skin test must be done, as RELIEF-COFF EXPECTORANT may affect the results of these tests.
- If you take atropine (e.g., eye drops) or medicines for depression (tricyclic antidepressants) as the effects of these medicines can become stronger.
- If you take monoamine oxidase inhibitors (medicines used to treat depression, e.g., tranylcypromine (Parnate) as it may increase the effect of RELIEF-COFF EXPECTORANT.
- The warning symptoms of damage to the ears caused by medicines such as aminoglycoside antibiotics, may be disguised by RELIEF-COFF EXPECTORANT.
- The sedative effect (feeling of drowsiness, memory loss, slow reflexes) of some medicines, e.g., alcohol, sleeping tablets, tables for anxiety or to relax your muscles, painkillers, and certain types of anti-depressants, may be increased.

RELIEF-COFF EXPECTORANT with alcohol

While taking RELIEF-COFF EXPECTORANT avoid alcoholic drinks.

Pregnancy and breastfeeding

RELIEF-COFF EXPECTORANT should not be taken when you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent RELIEF-COFF EXPECTORANT may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which RELIEF-COFF EXPECTORANT affects you.

RELIEF-COFF EXPECTORANT contains sodium methyl paraben.

It may cause allergic reactions (possibly delayed).

RELIEF-COFF EXPECTORANT contains 7,69 mg sodium per 5ml.

This is less than 1 mmol sodium (23 mg) per 5 ml and is to say essentially ‘sodium-free’.

RELIEF-COFF EXPECTORANT contains 20 mg propylene glycol in each 5 ml.

3. How to take RELIEF-COFF EXPECTORANT

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

Always take RELIEF-COFF EXPECTORANT exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

The usual dose is:

Adults:	5 to 10 ml every three to four hours.
Children 6 to 12 years:	2,5 to 5 ml every four hours.

RELIEF-COFF EXPECTORANT should not be used in children under the age of 6 years.

If you take more RELIEF-COFF EXPECTORANT than you should

In the event of an overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

An overdose may be fatal, and you may need urgent medical assistance.

If you forget to take a dose of RELIEF-COFF EXPECTORANT

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

RELIEF-COFF EXPECTORANT can have side effects.

Not all side effects reported for RELIEF-COFF EXPECTORANT are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking RELIEF-COFF EXPECTORANT, please consult your health care provider for advice.

If any of the following happens, stop taking RELIEF-COFF EXPECTORANT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash or itching, swelling of the face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

If you have them, you may have had an allergic reaction to RELIEF-COFF 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:

- faster or irregular heartbeat
- convulsions or seizures
- difficulty urinating or inability to pass urine

Tell your doctor if you notice any of the following:

Frequent side effects

- drowsiness
- dizziness
- headache
- paradoxical stimulation (effect that is opposite to what is excepted)
- slowness in movement or speech
- thick phlegm
- dry mouth
- stomach pain
- nausea
- weakness, lack of energy and strength

Less frequent side effects

- irritability
- hallucination (seeing, hearing, smelling things that do not exist)
- nervousness
- confusion
- tingling (pins and needles)
- nightmares
- inability to concentrate
- depression

- euphoria (unrealistic feeling of well-being)
- insomnia
- tremors (shaking)
- muscle twitching
- blurred vision
- tinnitus (ringing in the ears)
- feeling your heart beat
- hypotension (low blood pressure)
- chest feeling tight
- dry nose
- epigastric pain (pain right below your ribs)
- diarrhoea
- anorexia (loss of appetite)
- constipation
- nausea, vomiting
- liver problems
- rash, hive (itchy, raised red wheals)
- photosensitivity (develop itchy or redness on sun-exposed areas of the skin)

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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of RELIEF-

COFF EXPECTORANT.

In addition, side effects can also be reported to info@pharmacorp.co.za.

5. How to store RELIEF-COFF EXPECTORANT

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in a cool, dry place in well closed containers.
- Do not use after the expiry date stated on the label.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What RELIEF-COFF EXPECTORANT contains

The active substances are diphenhydramine hydrochloride, ammonium chloride, sodium citrate.

The other ingredients are caramel colour (E 150), hypromellose (E 464), menthol, propylene glycol (E 1520), raspberry flavour, saccharin sodium (E954), sodium methyl paraben (E219), purified water.

What RELIEF-COFF EXPECTORANT looks like and contents of the pack

RELIEF-COFF EXPECTORANT is a clear, brown solution, free from visible particles, with an odour characteristic of menthol.

RELIEF-COFF EXPECTORANT are packed in:

100 ml or 200 ml HDPE bottles with white LDPE snap on caps or 100 ml or 200 ml round, amber plastic (PET – Polyethylene Terephthalate) bottles with a white polypropylene (PP) screw cap with liner.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised on

17 February 2025

Registration number

27/10.1/0140

Access to the corresponding Professional Information

To be confirmed