

Patient Information Leaflet

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

CLEAR COUGH®SYRUP

diphenhydramine hydrochloride; ammonium chloride, sodium citrate

Contains sugar:

Sucrose: 1,5 g/ 5ml

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

CLEAR COUGH®SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use CLEAR COUGH®SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CLEAR COUGH®SYRUP 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 CLEAR COUGH®SYRUP is and what it is used for
2. What you need to know before you take CLEAR COUGH®SYRUP
3. How to use CLEAR COUGH®SYRUP
4. Possible side effects
5. How to store CLEAR COUGH®SYRUP
6. Contents of the pack and other information

1. What clear cough® syrup is and what it is used for

CLEAR COUGH[®] SYRUP contains the active substances diphenhydramine hydrochloride; ammonium chloride and sodium citrate.

CLEAR COUGH[®] SYRUP is used for the alleviation of cough.

2. What you need to know before you take CLEAR COUGH[®] SYRUP

Do not take CLEAR COUGH[®] SYRUP:

- If you are hypersensitive (allergic) to diphenhydramine hydrochloride; ammonium chloride and sodium citrate or any of the other ingredients of CLEAR COUGH[®] SYRUP listed in section 6. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are pregnant and breastfeeding your baby
- If you have impaired liver or kidney function
- If you are having an asthma attack
- If you are under 6 years old
- If you have porphyria (characterised by severe abdominal pain, chest pains, legs or back pain, constipation or diarrhoea, nausea or vomiting, muscle pain, tingling, numbness, weakness or paralysis, red or brown urine, mental changes such as anxiety, confusion, hallucinations, disorientation or paranoia, breathing problems, urination problems, rapid or irregular heartbeats (palpitations), high blood pressure, seizures)
- If you are taking or have recently taken (within the last two weeks) another antidepressant drug known as a monoamine oxidase inhibitor (MAOI). You should not take CLEAR COUGH[®] SYRUP at the same time as or within two weeks of stopping irreversible MAO inhibitors. Also do not take MAO inhibitors for at least one week after stopping CLEAR COUGH[®] SYRUP

Warnings and precautions

Take special care with CLEAR COUGH®SYRUP :

- If you are using alcohol, or if you are taking other medicines such as sedatives, tranquilisers or sleeping tablets, as it may lead to drowsiness and impaired concentration. You should take care not to drive or operate machinery, particularly at the start of treatment, as this may lead to accidents (see **driving and using machines**)
- If cough persists for more than 1 week, tend to recur or is accompanied by high fever, rash or persistent headache, consult a doctor.
- If you have heart failure disease, cardiovascular disease and irregular heartbeat.
- If you have peripheral oedema (swelling of feet and hands due to retained fluid) and pulmonary oedema (excessive fluid accumulated in the lungs)
- If you have toxæmia of pregnancy (serious abnormalities during pregnancy, associated with high blood pressure)
- If you have had any past or present liver or kidney disease
- If you have increased pressure in the eye (glaucoma)
- If you have enlarged prostate gland (prostatic hypertrophy).
- In patients with urinary retention
- If you have any allergies
- The elderly patients, are particularly prone to dizziness, sedation, confusion, hypotension (low blood pressure) and anticholinergic effects (dry mouth, blurry vision, dry eyes, constipation, or urinary problems)
- If you are taking or plan to take any medicine, even those you get without a prescription or traditional medicines

Other medicines and CLEAR COUGH®SYRUP

Always tell your healthcare provider if you or your child is taking any other medicine (this includes all complementary or traditional medicines)

Care should be taken if concomitantly taking CLEAR COUGH®SYRUP with:

- Nervous system depressants such as alcohol, barbiturates, hypnotics (causes sleep), narcotic analgesics (dependence producing substances used for the relief of pain), sedatives (for calming) and tranquillisers (medicines used for calming nerves) and
- anticholinergic medicines (a substance used to stop the release of certain nerve impulses involving acetylcholine),
- Tricyclic antidepressants as their effects may be enhanced by diphenhydramine.
- Antidepressants such as Monoamine-oxidase inhibitors (MAOIs) will potentiate both the drowsiness effect and the anticholinergic effects of diphenhydramine, therefore, COUGH®SYRUP should not be taken concurrently with patients taking MAOIs or within 14 days of stopping therapy with MAOIs.
- The effects of medicines with anticholinergic activity such as tricyclic antidepressants or maprotiline will be potentiated.
- Ototoxic medicines (medicines that causes damage to the ear) may be masked by diphenhydramine.

CLEAR COUGH®SYRUP with food, drink and alcohol

You should not drink alcohol while taking this medicine, as this medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol.

Pregnancy, breastfeeding and fertility:

CLEAR COUGH®SYRUP should not be taken during pregnancy or breastfeeding (see **Do not use CLEAR COUGH®SYRUP**).

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 healthcare provider for advice before taking CLEAR COUGH® SYRUP

Driving and using machines

The use of CLEAR COUGH® SYRUP leads to drowsiness and impaired concentration which is aggravated by the simultaneous intake of alcohol and it is unsafe to drive a vehicle or be in charge of machinery while using this medicine, as impaired decision making could lead to an accident

CLEAR COUGH® SYRUP contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take CLEAR COUGH® SYRUP:

Taking your medicine:

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

Always take CLEAR COUGH® SYRUP 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.

A maximum of four doses per day should not be exceeded.

The usual dose is:

ADULTS:

One to two medicine measures (5 – 10 ml) every three to four hours.

CHILDREN: 6 to 12 years:

Half to one medicine measure (2, 5 - 5 ml) every four hours.

CLEAR COUGH® SYRUP should not be given to children under 6 years.

If you take more CLEAR COUGH® SYRUP than you should:

Treatment is symptomatic and supportive.

You might experience an increase in side effects in the event of taking more CLEAR COUGH® SYRUP than the recommended dosage.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take the carton and bottle with you. This is so the doctor knows what you have taken.

If you forget to take CLEAR COUGH® SYRUP:

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

4. Possible side effects

CLEAR COUGH® SYRUP can have side effects.

Not all side effects reported for CLEAR COUGH® SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking CLEAR COUGH®

SYRUP, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking/using CLEAR COUGH® SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital :

- if you get swelling of the hands, feet, ankles, face, lips or throat, which may cause difficult in swallowing or breathing.
- if you could notice an itchy, nettle rash (urticaria). This may mean that you are having an allergic reaction to CLEAR COUGH® SYRUP.
- Fainting

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to CLEAR COUGH® SYRUP. You or your child may need urgent medical attention or hospitalisation

Tell your doctor if you notice any of the following:

Frequent side effects

- sedation which includes drowsiness (feeling sleepy),
- inability to concentrate,
- lassitude (lack of energy/fatigue),
- dizziness,
- hypotension (low blood pressure),
- muscular weakness and incoordination

Less frequent side effects:

- Headache, heart palpitations, pale skin, confusion, back pain, abdominal pain as a combination of these symptoms may be due to abnormal red blood cell (Haemolytic anaemia),
- Sore mouth or skin, sore throat, cough, trouble breathing, feeling light-headed, fever, chills, or body aches as a combination of these symptoms may be due to abnormal white blood cell (leukopenia),
- Bleeding gums, nosebleeds, rashes, blood in urine, excessive and easy bleeding from wounds, bruising, fatigue and general weakness as a combination of these symptoms may be due to abnormal blood cell (thrombocytopenia),
- anorexia (lack of appetite),
- blurred vision
- ringing in the ear (tinnitus)
- elation (high spirit)

- depression
- Irritability
- nightmares
- dry mouth
- tightness of chest
- tingling
- heaviness and weakness of the hands
- constipation (infrequent bowel movement)
- diarrhoea (frequent or loose watery stools)
- pain in the upper and middle region of stomach
- nausea (feeling that one is about to vomit)
- having fits
- unrealistic feeling of well-being (euphoria)
- restlessness
- sensitisation of the skin to sunlight (photosensitisation)
- inability to sleep (insomnia)
- nervousness
- increased heartbeat
- shaking
- muscle twitching
- thirst
- abnormally deep and rapid breathing
- progressive drowsiness
- mental confusion
- difficulty in passing urine

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 CLEAR COUGH® SYRUP.

5. How to store CLEAR COUGH® SYRUP

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Do not freeze
- Store your medicine in the original packaging in order to protect from light.
- Do not use this medicine after the expiry date shown on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What CLEAR COUGH® SYRUP contains

The active substance is diphenhydramine hydrochloride; ammonium chloride, sodium citrate.

Alcohol 0,1% v/v

Preservatives

Nipastat 0,02 % m/v

The other ingredients are:

Alcohol, chloroform spirits, clarks caramel, menthol, nipastat, purified water, sodium carboxymethyl cellulose, sucrose,

**WHAT CLEAR COUGH® SYRUP LOOKS LIKE AND
CONTENTS OF THE PACK**

A brown syrupy liquid

100 ml, 200 ml, 2,5 litre and 25 litre containers

Holder Of Certificate Of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

1724

This Leaflet Was Last Revised In

22 November 2022

8. REGISTRATION NUMBER(S)

W/10.1/367(SA)

S2	BOT 0500758 (Botswana) (100 ml)
NS1	90/10.1./00372 (Namibia) (100 ml, 200 ml, 2.5 litres)