

SCHEDULING STATUS

S2

BETALIN®

Diphenhydramine hydrochloride, Ammonium chloride,

Sodium citrate

Contains sugar:

Sucrose 1,3 g per 5 ml

Read all of this leaflet carefully before you start taking BETALIN®

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

- Keep this leaflet. You may need to read it again.
- Do not share BETALIN® 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.

What is in this leaflet

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

1. What BETALIN® is and what it is used for

BETALIN® contains the active substances diphenhydramine hydrochloride; ammonium chloride and sodium citrate.

BETALIN® is used for the alleviation of cough.

2. What you need to know before you use BETALIN®

Do not use BETALIN® :

- If you are hypersensitive (allergic) to diphenhydramine hydrochloride; ammonium chloride and sodium citrate or any other ingredients of BETALIN® (listed in **section 6**).
- If you are pregnant and breastfeeding your baby
- If you have impaired liver or kidney function
- During asthma attack
- For children 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) .

Warnings and precautions

Special care should be taken with BETALIN®:

- 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
- 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.

Children and adolescents

BETALIN® should not be given to children, under 6 years old (see section **Do not use BETALIN®**).

Other medicines and BETALIN®

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

Care should be taken if concomitantly taking BETALIN® 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, BETALIN®

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.

BETALIN® 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

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

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

The use of BETALIN® 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.

BETALIN® contains sugar in the form of Sucrose.

BETALIN® may be harmful to the teeth and If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BETALIN®.

3. How to use BETALIN®

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

Always take BETALIN® exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you. Check with your doctor or, pharmacist or nurse if you are not sure.

The usual dose is:

Children: 6 to 12 years: A half to one medicine measure (2,5 ml – 5 ml) every four hours.

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

BETALIN® should not be given to children under 6 years (see section 2, **Do not use BETALIN®**)

If you use more BETALIN® you should

If you take more BETALIN® than you should, you may experience an increase in side effects listed below (see **section 4**).

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

If you forget to use BETALIN®

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

Always take BETALIN® as directed. If you forget a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see **section 3**).

4. Possible side effects

BETALIN® can have side effects.

Not all side effects reported for BETALIN® are included in this leaflet. Should your general health worsens or if you experience any untoward effects while taking BETALIN®, please consult your health care provider for advice.

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to BETALIN®. You 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)
- Vomiting
- 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

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 BETALIN.

5. How to store BETALIN®

- Store all medicines out of reach of children.
- Keep the container in the outer carton
- Keep the container tightly closed
- Do not use after the expiry date stated on the label / carton / bottle
- 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 BETALIN® contains

The active substances are 14 mg Diphenhydramine hydrochloride, 136 mg Ammonium chloride, 56 mg Sodium citrate

Sucrose 1,3 g

Preservative: Nipastat 0,02 % *m/v*

The other ingredients are:

Clarks caramel 48000, essence of raspberry no. 1, invert, menthol, nipastat, propylene glycol, purified water, sodium citrate, sucrose

What BETALIN® looks like and contents of the pack

A brown syrupy liquid.

100 ml, 200 ml, 2,5 L and 25 L containers.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Laurre Road

Stormill Ext. 1

Roodepoort 1724

South Africa

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Registration numbers

L/10.1/415 (S.A.)

S3

BOT 0500773 (Botswana) (100 ml)

NS1

90/10.1/00366 (Namibia) (100 ml, 200 ml, 2,5 L, 25 L)