

1.3.2 Current Approved Patient Information Leaflet for Human Medicines

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

BETAPHLEM SYRUP (250 mg / 5 ml)

Carbocisteine

Contains sugar: Sucrose 1,9 g per 5 ml

Glycerin 390 mg per 5 ml

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

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

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

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

1. What BETAPHLEM SYRUP is and what it is used for

BETAPHLEM SYRUP belongs to a group of medicines called mucolytics. It works by making the mucus less sticky. This makes the mucus easier to expectorate when coughing. BETAPHLEM SYRUP is used for problems in the airways when there is too much of mucus or when it is too sticky.

2. What you need to know before you take BETAPHLEM SYRUP

Do not take BETAPHLEM SYRUP:

- if you are hypersensitive (allergic) to carbocysteine or any of the other ingredients of BETAPHLEM SYRUP
- if you are pregnant
- if you have active peptic ulcer (burning stomach pain, heartburn, nausea)
- if you are taking a cough mixture containing pholcodeine

Warnings and precautions

Take special care with BETAPHLEM SYRUP:

- if you have a history of gastric or duodenal ulcer (nausea, burning stomach pain, heartburn, feeling of fullness, bloating)
- if you have asthma with a history of bronchospasm (coughing, tightness in chest, trouble breathing)
- if you have experience coughing up mucus, wheezing, fatigue

Children

Do not give BETAPHLEM SYRUP to children under 2 years because it is unlikely to be safe.

Other medicines and BETAPHLEM SYRUP

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

Take care if you are using any of the following medicines with BETAPHLEM SYRUP

- BETAPHLEM SYRUP should not be taken with pholcodeine linctus

Pregnancy, breast-feeding and fertility

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 this medicine.

Pregnancy:

It is not recommended to use in pregnant woman as the safety of BETAPHLEM SYRUP in pregnancy has not been established.

Driving and using machines

BETAPHLEM SYRUP has no effect on the ability to drive and use machines.

BETAPHLEM SYRUP contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BETAPHLEM SYRUP.

BETAPHLEM SYRUP contains methyl parahydroxybenzoate

May cause allergic reactions (possibly delayed).

3. How to take BETAPHLEM SYRUP

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

Always take BETAPHLEM SYRUP exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Not recommended for children under 2 years.

Adults: Two to three medicine measures (10 ml to 15 ml), three times daily.

Children: 6 - 12 years: One medicine measures (5 ml) three times daily.

Children: 2 - 5 years: A quarter to half a medicine measures (1,25 - 2,5) ml four times daily, according to age

If you take more BETAPHLEM SYRUP than you should

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 take BETAPHLEM SYRUP

If you miss a dose, take it as soon as you remember, but if it is within 4 hours of your next dose, skip the dose you missed and take the next one at the usual time. Then continue your treatment as before.

Do not take a double dose to make up for a missed dose.

If you stop taking BETAPHLEM SYRUP

If you are unsure when to stop using BETAPHELM SYRUP, consult your doctor or pharmacist.

If you have any further questions on the use of this product, ask your doctor your pharmacist.

4. Possible side effects

BETAPHLEM SYRUP can have side effects.

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

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

- rash, itching, problems swallowing or breathing, swelling of the lips, face, throat or tongue,
- blistering or bleeding of the skin including around your lips, eyes mouth, nose and genitals.

These are all very serious side effects. If you have them, you may have had a serious reaction to BETAPHLEM SYRUP. 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:

- blood in your vomit or black starry stools.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- nausea (feeling sick)
- diarrhoea
- allergic reactions such as hives
- tightness in chest
- coughing
- wheezing

- trouble breathing
- headache
- muscle pain
- dizziness
- leaking urine
- abnormal heart beat
- breathlessness

Unknown side effects:

- skin rash
- fatigue (tiredness)
- weight gain
- stomach pain

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. 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 BETAPHLEM SYRUP.

5. How to store BETAPHLEM SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a cool place, protected from light.

Do not use after the expiry date stated in the packaging material.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What BETAPHLEM SYRUP contains

BETAPHLEM SYRUP

The active substance is carbocisteine.

The other ingredients are:

Cherry essence no. 1, citric acid, glycerin, hydrochloric acid, methyl hydroxybenzoate, poncea 4R Supra (W.G. 709) C.I. 16255, purified water, sodium citrate, sodium hydroxide, sucrose.

What BETAPHLEM SYRUP looks like and contents of the pack

Red, syrupy liquid with a sweet cherry flavour.

200 ml and 2,5 litre bottles.

Holder of Certificate of Registration

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