PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

BABY'S OWN COUGH SYRUP

45,52 mg ammonium chloride per 5 ml syrup

Contains preservatives: 2,49 mg methylparaben and 0,521 mg benzoic acid per 5 ml syrup

Contains sugar: 1,87 g glucose and 2,80 g sucrose per 5 ml syrup.

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

BABY'S OWN COUGH SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use BABY'S OWN COUGH SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BABY'S OWN COUGH SYRUP 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 10 days

What is in this leaflet

1. What BABY'S OWN COUGH SYRUP is and what it is used for
2. What you need to know before you use BABY'S OWN COUGH SYRUP

3. How to use BABY'S OWN COUGH SYRUP
4. Possible side effects
5. How to store BABY'S OWN COUGH SYRUP
6. Contents of the pack and other information

1. What BABY'S OWN COUGH SYRUP is and what it is used for

BABY'S OWN COUGH SYRUP is used for the temporary relief/alleviation of cough.

2. What you need to know before you take BABY'S OWN COUGH SYRUP

Do not take BABY'S OWN COUGH SYRUP

- If you are hypersensitive (allergic) to ammonium chloride or any of the ingredients of BABY'S OWN COUGH SYRUP (listed in section 6).
- If you have kidney or liver insufficiencies.

Warnings and precautions

WARNING:

BABY'S OWN COUGH SYRUP contains CAMPHOR (as flavourant). Use only as directed – excess quantities may be harmful if swallowed. Keep out of the reach of children.

Special care should be taken with BABY'S OWN COUGH SYRUP:

- If you have high blood pressure or a heart disease, because BABY'S OWN COUGH SYRUP may lead to high blood pressure, water retention and electrolyte abnormalities.

Persistent coughs should be investigated for possible underlying cause by your doctor.

BABY'S OWN COUGH SYRUP contains camphor as a flavourant. Avoid use in pregnancy (see **Pregnancy and breastfeeding**), epilepsy, and chronic lung conditions. Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

Children

Do not give BABY'S OWN COUGH SYRUP to children under 2 years of age.

Other medicines and BABY'S OWN COUGH SYRUP

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

Pregnancy and breastfeeding

The safety of BABY'S OWN COUGH SYRUP in pregnancy and lactation has not been established. Use is not recommended (see **Warnings and precautions**).

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

Large doses of BABY'S OWN COUGH SYRUP may cause drowsiness and interfere with your ability to drive or use machinery.

BABY'S OWN COUGH SYRUP contains benzoic acid, methylparaben, sugar and Carmoisine.

Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Do not give BABY'S OWN COUGH SYRUP to children under 2 years of age.

BABY'S OWN COUGH SYRUP contains sucrose and glucose, which may have an effect on the blood sugar levels of diabetic patients.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BABY'S OWN COUGH SYRUP.

BABY'S OWN COUGH SYRUP contains methylparaben as preservative and Carmoisine CI 14720 as colourant. These ingredients may cause allergic reactions.

3. How to take BABY'S OWN COUGH SYRUP

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

Always take BABY'S OWN 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.

Doses must be taken with an adequate amount of fluid (half to one glass).

Shake the bottle well before use.

The usual dose, to be given orally 2 to 4 hourly is as follows:

Children:

2 to 6 years: 7,5 ml in water

6 to 12 years: 15 ml in water

Adults:

15 ml to 30 ml in water

If you take or give more BABY'S OWN COUGH SYRUP than you should

Large doses of BABY'S OWN COUGH SYRUP may cause:

- Nausea
- Vomiting
- Thirst
- Headache
- Abnormally deep and rapid breathing, breathing is difficult and the breath has a characteristic odour, kidney failing to produce urine may occur (anuria)
- A feeling of warmth

- Muscle twitching
- Progressive drowsiness, delirium (confusion) and dizziness
- Recurrent fits
- Depression of the central nervous system and coma
- Gastric (stomach) irritation and abdominal pain (colic)
- Abnormal high body fluid and tissue acidity (acidosis)
- Abnormal low doses of potassium in the blood (hypokalaemia)
- The capacity of the liver to convert ammonium ion to urea is exceed (hepatic encephalopathy).

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

If you forget to take BABY'S OWN COUGH SYRUP

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

4. Possible side effects

BABY'S OWN COUGH SYRUP can have side effects.

Stop taking BABY'S OWN COUGH SYRUP and immediately report to your doctor or the emergency department of the nearest hospital if you develop any of the following serious side effects:

- Those for which the frequency is not known:

- A combination of the following symptoms: confusion, rapid or deep breathing ("air hunger"), fast heartbeat, fatigue, nausea and vomiting, and weakness as this may be due high blood acidity.
- A combination of the following symptoms: muscle weakness, fatigue, cramping and constipation, sometimes with palpitations or an irregular heartbeat as this may be due to low potassium levels.

These are all very serious side effects. If you have them, you may have had a serious reaction to BABY'S OWN COUGH SYRUP. You may need urgent medical attention.

Stop taking BABY'S OWN COUGH SYRUP and report to your doctor as soon as possible if you develop any of the following side effects:

- Those for which the frequency is not known:
  - Shortness of breath with rapid breathing accompanied by light-headedness, dizziness, a fast heartbeat and numbness or tingling as this may be due to hyperventilation.

This side effect may require medical attention.

Tell your doctor if the following side effects continue or become bothersome:

- Those for which the frequency is not known:
  - Headache
  - Progressive drowsiness
  - Nausea and vomiting
  - Thirst.

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

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BABY'S OWN COUGH SYRUP.

Side effects may also be reported to Mentholatum Customer Care at www.mentholatum.co.za.

5. How to store BABY'S OWN COUGH SYRUP

Store all medicines out of reach of children.

Store at or below 25 ºC and protect from light.

Do not use after the expiry date stated on the label.

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 BABY'S OWN COUGH SYRUP contains

- The active substance is 45,52 mg ammonium chloride per 5 ml syrup.
- The preservatives are methylparaben 0,05 % *m/v* and benzoic acid 0,01 % *m/v*.
- The other ingredients are anise oil, camphor, Carmosine, Clark's Caramel, glacial acetic acid, liquorice liquid extract, purified water and strong ammonia solution.
- BABY'S OWN COUGH SYRUP contains 1,87 g glucose and 2,80 g sucrose per 5 ml syrup.

What BABY'S OWN COUGH SYRUP looks like and contents of the pack

BABY'S OWN COUGH SYRUP is a red syrupy liquid.

BABY'S OWN COUGH SYRUP is presented in glass bottles of 50 ml, 100 ml and 200 ml

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

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This leaflet was last revised in

September 2025

Application number

G600 (Act 101/1965)

Access to the corresponding Professional Information

The PI can be found online under Mentholatum SA's website at https://www.mentholatum.co.za/product-information/ or on SAHPRA's online directory at https://medsinfo.sahpra.org.za/home.