

PROFESSIONAL INFORMATION

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1. NAME OF THE MEDICINE

BABY'S OWN COUGH SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syrup contains:

Ammonium chloride 45,52 mg

Preservatives:

Methylparaben 2,49 mg (0,05 % *m/v*)

Benzoic acid 0,521 mg (0,01 % *m/v*)

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

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Shake well before use.

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

Children:

2 to 6 years: 7,5 ml every 2 to 4 hours in water.

6 to 12 years: 15 ml every 2 to 4 hours in water.

Adults:

15 ml to 30 ml every 2 to 4 hours in water.

Method of administration

Doses must be taken orally.

4.3 Contraindications

Hypersensitivity to ammonium chloride or any of the ingredients of BABY'S OWN COUGH SYRUP.

BABY'S OWN COUGH SYRUP is contra-indicated in patients with hepatic or renal impairment.

4.4 Special warnings and precautions for use

Persistent coughs should be investigated for possible underlying cause by the patient's doctor.

Liquorice may cause reversible sodium retention and potassium loss leading to hypertension, water retention and electrolyte imbalance.

Use with caution in patients with heart disease.

BABY'S OWN COUGH SYRUP contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take BABY'S OWN COUGH SYRUP.

BABY'S OWN COUGH SYRUP contains glucose and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

BABY'S OWN COUGH SYRUP contains 0,521 mg benzoic acid in each 5 ml dosage unit. Benzoic acid may increase jaundice in newborn babies (up to 4 weeks old) and should therefore not be used in children under 2 years of age.

BABY'S OWN COUGH SYRUP contains Carmoisine CI 14720 as colourant that may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of this preparation in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Possible side effects include:

Gastrointestinal disorders:

Frequency unknown: nausea and vomiting

General disorders and administrative site conditions:

Frequency unknown: acidosis and hypokalaemia.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Large doses of BABY'S OWN COUGH SYRUP may cause nausea, vomiting, thirst, headache, abnormally deep and rapid breathing and progressive drowsiness, gastric irritation, acidosis and hypokalaemia. If the capacity of the liver to convert ammonium ion to urea is exceeded, hepatic encephalopathy may ensue.

Large doses of camphor may cause nausea, vomiting, dizziness, colic, headache, a feeling of warmth, delirium, muscle twitching, recurrent fits, depression of the central nervous system and coma. Breathing is difficult and the breath has a characteristic odour; anuria may occur.

Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 10.1 Antitussives and expectorants.

Expectorants are considered to increase the volume of secretions in the respiratory tract thereby facilitating their removal by ciliary action and coughing, achieved by a reflex irritant effect on the gastric mucosa.

5.2 Pharmacokinetic properties

Ammonium chloride is absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver. The anion is thus liberated into the blood and extracellular fluid causes a metabolic acidosis and decrease the pH of the urine. This is followed by transient diuresis.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Camphor,
liquorice liquid extract,
Anise oil,
Glacial acetic acid,
strong ammonia solution 25 %,
methyl hydroxybenzoate,
benzoic acid,
syrup simplex (sucrose),
liquid glucose,
Carmoisine C/I No 14720,
Clark's Caramel C/I No 4800 and
purified water.

6.2 Incompatibilities

None known.

Mentholatum SA (Pty) Ltd
Baby's Own Cough Syrup
45,52 mg Ammonium chloride per 5 ml syrup

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

BABY'S OWN COUGH SYRUP is filled into 50 ml, 100 ml or 200 ml round amber glass bottles. The bottles are closed with a polypropylene cap.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mentholatum South Africa (Pty) Ltd

1st Floor, Silverberg Terrace

Steenberg Office Park

Silverwood Close

Tokai

7945

8 REGISTRATION NUMBER

G600 (act 101/1965)

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

28 November 2019

Mentholatum SA (Pty) Ltd
Baby's Own Cough Syrup
45,52 mg Ammonium chloride per 5 ml syrup

10 DATE OF REVISION OF THE TEXT

15 May 2023