

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SACCHEROI SYRUP 135 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Sodium Bicarbonate 135 mg

Ethyl Alcohol (96,0 %) 6,16 % *v/v*

Preservatives:

Methyl paraben 0,0838 % *m/v*

Propyl paraben 0,0400 % *m/v*

Contains sugar: Sucrose 3 326 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Syrup

A reddish-brown mixture of medium viscosity.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SACCHEROI SYRUP is indicated for use as an antacid in infants and children up to 10 years.

4.2 Posology and method of administration

Posology

SHAKE THE BOTTLE BEFORE USE.

Take three to four times a day with water.

Children:

0 – 6 months: 7,5 ml (1½ medicine measuresful)

6 months – 1 year: 10 ml (2 medicine measuresful)

1 – 2 years: 15 ml (3 medicine measuresful)

3 – 5 years: 20 ml (4 medicine measuresful)

6 – 10 years: 30 – 35 ml (6 – 7 medicine measuresful)

Do not give more than three to four times per 24 hour period.

Do not give this medicine to babies with a body mass less than 2,5 kg (see section 4.3).

IF YOU MISS GIVING A DOSE, SKIP THE MISSED DOSE. DO NOT DOUBLE THE DOSES.

Do not use the maximum dosage of this product for more than two weeks, except under the advice and supervision of a doctor (see section 4.4).

Method of administration

For oral use only.

4.3 Contraindications

SACCHEROI SYRYP is contraindicated in:

- patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria;
- babies with a body mass less than 2,5 kg;

- patients who are hypersensitive to sodium bicarbonate or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not use the maximum dosage of this product for more than two weeks, except under the advice and supervision of a doctor.

SACCHEROI SYRUP should be administered extremely cautiously to patients with congestive heart failure, oedema, renal impairment, cirrhosis of the liver or hypertension, aldosteronism, and to patients receiving corticosteroids.

Methyl paraben and propyl paraben may cause allergic reactions (possibly delayed).

This medicine contains 0,30824 ml of alcohol (ethanol 96 %) in each 5 ml.

The small amount of alcohol in this medicine will not have any noticeable effects.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take SACCHEROI SYRUP.

4.5 Interaction with other medicinal products and other forms of interaction

Sodium bicarbonate may increase or decrease the effects of a number of medicines due to raising gastric pH and the alkalinisation of the urine.

Alkalinisation of the urine by sodium bicarbonate leads to increased renal clearance of acidic medicines such as salicylates, tetracyclines, barbiturates.

Alkalinisation of the urine may also affect the elimination of sympathomimetics, anticholinergics, tricyclic antidepressants, H₂-blockers, captopril and quinidine.

Lithium excretion is enhanced.

Most interactions can be avoided by taking antacids 2 hours before or after ingestion of other medicines.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no data available on the effects of SACCHEROI SYRUP on pregnancy as this product is not intended for use during pregnancy.

Breastfeeding

There is no data available on the effects of SACCHEROI SYRUP on breastfeeding as this product is not intended for use during breastfeeding.

Fertility

There is no data available on the effects of SACCHEROI SYRUP on fertility.

4.8 Undesirable effects

Gastrointestinal disorders

Frequency unknown: Stomach cramps, flatulence and belching.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. 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

Excessive administration may lead to metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include shortness of breath, muscle weakness, restlessness, convulsions and coma.

Hyperkalaemia may occur in patients with renal failure.

Muscle hypertonicity, twitching, and tetany may develop especially in hypocalcaemic patients.

Treatment of metabolic alkalosis and hypernatraemia associated with sodium bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride and potassium ions may be of particular importance.

Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

11.4.1 Antacids – Acid Neutralisers

Pharmacotherapeutic group: Antacids with sodium bicarbonate

ATC code: A02AH

Sodium bicarbonate has acid neutralizing properties by diminishing the activity of pepsin in gastric secretion.

5.2 Pharmacokinetic properties

Sodium bicarbonate causes neutralization of gastric acid with the production of carbon dioxide. Bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions are excreted in the urine, which is rendered alkaline, and there is an accompanying diuresis.

The very water-soluble sodium bicarbonate is rapidly absorbed from the stomach and presents both an alkali and a sodium load.

Antacids are cleared from the empty stomach in approximately 30 minutes. However, the presence of food is sufficient to elevate gastric pH and to prolong the neutralising effects of antacids for approximately 2-3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel 48000

Chloroform

Ethyl Alcohol 96,0 %

Glycerine

Methyl paraben (E218)

Propyl paraben (E217)

Purified water

Sucrose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a well-closed container at or below 25 °C.

Keep bottle in unit carton until prior to use.

6.5 Nature and contents of container

100 ml PVC bottle with a white LDPE cap, contained in an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

E/11.4.1/1139

9. DATE OF FIRST AUTHORISATION

03 October 1995

10. DATE OF REVISION OF THE TEXT

21 February 2024