

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

SACCHEROI SYRUP, 135 mg, syrup

Sodium Bicarbonate

Contains sugar: Sucrose 3 326 mg

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share SACCHEROI 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 symptoms worsen or do not improve after a few days.

What is in this leaflet

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

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

This medicine contains sodium bicarbonate, which neutralizes stomach acid.

It is used as an antacid in infants and children up to 10 years of age.

2. What you need to know before you use SACCHEROI SYRUP

Do not use SACCHEROI SYRUP:

- if your child is hypersensitive (allergic) to sodium bicarbonate or any of the ingredients of SACCHEROI SYRUP (listed in section 6);
- if your baby weighs less than 2,5 kg;
- if your child has raised alkali level in the body or lungs, calcium deficiency, or reduced production of stomach acid.

Warnings and precautions

Take special care with SACCHEROI SYRUP:

- if your child suffers from heart failure, water retention, kidney problems, liver damage or high blood pressure;
- if your child suffers from a condition where the adrenal glands produce too much aldosterone;
- if your child is receiving corticosteroid medication.

If your child's health worsens while taking SACCHEROI SYRUP, see a doctor or pharmacist.

Other medicines and SACCHEROI SYRUP

Always tell your healthcare provider if you are administering any other medicine.

(This includes complementary or traditional medicines).

- SACCHEROI SYRUP may interact with a number of medicines including salicylates (such as aspirin), tetracycline antibiotics, barbiturates (for epilepsy), sympathomimetics (such as pseudoephedrine), anticholinergics (such as ipratropium bromide), tricyclic antidepressants, H₂-blockers (for acid reflux and stomach ulcers), captopril (for high blood pressure), quinidine (for irregular heartbeat) and lithium (for mood disorders).

Most interactions can be avoided by taking it 2 hours before or after other medicines.

Pregnancy, breastfeeding and fertility

There is no data available on the effects of SACCHEROI SYRUP on pregnancy, breastfeeding or on fertility as this product is not intended for use during pregnancy, breastfeeding or by women of childbearing potential.

SACCHEROI SYRUP contains ethyl alcohol, methyl paraben, propyl paraben, and sucrose

- This medicine contains 236,7 mg of alcohol (ethanol) in each 5 ml which is equivalent to 4,73 % *m/v*. The amount in 5 ml of this medicine is equivalent to less than 6 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Methyl paraben and propyl paraben may cause allergic reactions (possibly delayed).
- If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving this medicine.

3. How to take SACCHEROI SYRUP

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

Always give SACCHEROI SYRUP exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is given three to four times a day by mouth with water.

Shake the bottle before use.

Age:	Dose:
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 in a 24 hour period.

Do not give to babies weighing less than 2,5 kg.

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

If you give more SACCHEROI SYRUP than you should

Symptoms of an overdose may include shortness of breath, muscle weakness, restlessness, fits and coma.

Excessive muscle contraction, twitching, and painful muscle spasms may develop especially in patients with a calcium deficiency.

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 give SACCHEROI SYRUP

Do not double the dose. Skip the missed dose and continue with the next dose as directed.

3. Possible side effects

SACCHEROI SYRUP can have side effects.

Not all side effects reported for SACCHEROI SYRUP are included in this leaflet.

Should your child's general health worsen or if your child experiences any untoward effects while receiving SACCHEROI SYRUP, please consult your child's health care provider for advice.

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

- shortness of breath,
- muscle weakness,
- restlessness,
- fits,
- coma.

These are all serious side effects. Your child may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency of side effects unknown:

- stomach cramps,
- flatulence (wind),
- burping.

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 “**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 SACCHEROI SYRUP.

5. How to store SACCHEROI SYRUP

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in a well-closed container.
- Keep bottle in unit carton until prior to use.
- 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 SACCHEROI SYRUP contains

- The active substance is sodium bicarbonate 135 mg per 5 ml syrup.
- The other ingredients are caramel, chloroform, glycerine, purified water.

Contains sugar: Sucrose 3 326 mg

Contains alcohol: Ethyl alcohol (96 %) 6,16 % v/v

Preservatives:

Methyl paraben (E218)

Propyl paraben (E217)

What SACCHEROI SYRUP looks like and contents of the pack

SACCHEROI SYRUP is a reddish-brown mixture of medium viscosity contained in a 100 ml PVC bottle with a white cap, in an outer carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

<https://www.avidbrands.co.za>

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