SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:

BABA C syrup

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

- BABA C is available without a doctor's prescription, as a health supplement. Nevertheless you still need to use BABA C carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share BABA C with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT BABA C CONTAINS:

The active substances are:	
Each 5 ml contains:	
Vitamin C	200 mg
Vitamin D ₃ equivalent to Vitamin D	25 i.u.
Contains sugar (glucose, sucrose)	2950 mg

Preservatives:	
Sodium Benzoate	0.2% m/v
Potassium Sorbate	0.2% m/v

The other ingredients are:

Beta carotene, citric acid, flavourant, glycerine, polyoxyl 40 hydrogenated castor oil, preservatives, propylene glycol, sodium citrate, sugar, water, xanthan gum.

2. WHAT BABA C IS USED FOR:

• **BABA C** is formulated as a Vitamin C and Vitamin D supplement.

3. BEFORE YOU TAKE BABA C:

Do not take BABA C:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of BABA C (see "WHAT BABA C CONTAINS").
- If you have a kidney disease or kidney problems.

Take special care with BABA C:

- If you have any diagnosed condition or are taking any other medication.
- If you are pregnant or breastfeeding your baby (see "PREGNANCY AND BREASTFEEDING").
- Do not exceed the recommended dosage.
- BABA C is not intended for use in children under the age of 1 year.

Taking BABA C with food and drink:

• **BABA C** should be taken with food.

Pregnancy and Breastfeeding:

- Do not take BABA C if you are pregnant or breastfeeding your baby.
- If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking this medicine.

Driving and using machinery:

• This product should not affect your ability to drive a vehicle or operate machinery requiring your attention.

Important information about some of the ingredients of BABA C:

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **BABA C**.
- BABA C contains sugar (glucose and sucrose), which may have an effect in the glycaemic control of patients with diabetes mellitus.

Taking other medicines with BABA C:

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

4. HOW TO TAKE BABA C:

- Do not share medicines prescribed to you with any other person.
- Always take **BABA C** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- Do not exceed the recommended dosage.
- For oral use only.

The usual dose is:

- Children: 1 6 years: 5 ml twice daily, or as prescribed by a healthcare provider.
- Shake well before use.

If you take more BABA C than you should:

- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
- Overdosage symptoms might include diarrhoea (runny, loose stool), gastrointestinal disturbances (upset stomach), headaches, fatigue (tiredness) and sleepiness.

If you forget to take/missed a dose of BABA C:

- Take the missed dose as soon as you remember.
- Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

• **BABA C** can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **BABA C**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Less frequent: Nausea (feeling nauseous).
- Less frequent: Abdominal cramps or stomach pains.
- Less frequent: Diarrhoea (runny, loose stool).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BABA C:

- STORE ALL MEDICINE OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Do not refrigerate/freeze.
- Store in the original package/container.
- Keep the container in the outer carton.
- Protect from light and moisture.
- Do not store in the bathroom.
- Keep tightly closed.
- Do not use after the expiry date stated on the carton.
- Do not use BABA C if you notice any discolouration of the syrup.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BABA C:

100 ml syrup, packed in a round, amber, glass bottle, with a screw on PVC cap.

8. IDENTIFICATION OF BABA C:

Cloudy, orange-coloured syrup with a sweet blackcurrant taste and vitamin odour.

9. REGISTRATION NUMBER/REFERENCE NUMBER: To be allocated upon registration.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Brunel Laboratoria (Pty) Ltd 1 Van Tonder Street Sunderland Ridge Centurion 0157 info@brunel.co.za www.brunel.co.za

11. DATE OF PUBLICATION:

To be allocated upon registration.

12. DATE OF REGISTRATION:

To be allocated upon registration.

13. COMPLEMENTARY MEDICINE:

Complementary Medicine – Health Supplement. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

The Professional Information for **BABA C** is available on <u>http://www.brunel.co.za/baba-c-syrup-100-ml/</u> or can be requested from the contact details above.

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