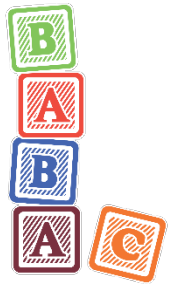


## PATIENT INFORMATION LEAFLET



### SCHEDULING STATUS

Will be allocated by SAHPRA upon registration.

### BABA C syrup

Ascorbic acid (vitamin C), cholecalciferol (vitamin D<sub>3</sub>).  
Preservatives: Sodium benzoate 0,2 % *m/v*, potassium sorbate 0,2 % *m/v*.  
Contains sugar: Each 5 ml contains 1 750 mg glucose and 1 200 mg sucrose.

### COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

**This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.**

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

BABA C is available without a doctor's prescription for you to maintain your child's health. Nevertheless, you still need to give your child BABA C carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

### What is in this leaflet

1. What BABA C is and what it is used for.
2. What you need to know before you give your child BABA C.
3. How to give your child BABA C.
4. Possible side effects.
5. How to store BABA C.
6. Contents of the pack and other information.

#### 1. What BABA C is and what it is used for

BABA C syrup is a vitamin C and D supplement for children, formulated for daily use as a factor in the maintenance of good health.

#### 2. What you need to know before you give your child BABA C

##### Do not give your child BABA C:

- if your child is hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of BABA C (see **What BABA C contains**).

### Warnings and precautions

BABA C is not intended for use in children under the age of 1 year.

### Other medicines and BABA C

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

### BABA C with food, drink and alcohol

See section 3 (**How to give your child BABA C**).

### Pregnancy, breastfeeding and fertility

BABA C is indicated for use in children.

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 healthcare provider for advice before taking BABA C.

Safety and efficacy of BABA C during pregnancy and breastfeeding have not been established.

### Driving and using machines

BABA C is not likely to affect your child's ability in performing tasks requiring their attention.

**BABA C contains preservatives:**

BABA C contains sodium benzoate and potassium sorbate.

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in new born babies (up to 4 weeks old).

**BABA C contains glucose and sucrose:**

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before giving your child BABA C.

BABA C may be harmful to your child's teeth.

**BABA C contains hydrogenated castor oil:**

BABA C contains hydrogenated castor oil which may cause stomach upset and diarrhoea.

**3. How to give your child BABA C**

Do not share your medicines with any other person.

Always give your child BABA C exactly as described in this leaflet, or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

*Children 1 – 6 years of age:* 5 ml twice daily, or as prescribed by a healthcare provider.

If you have the impression that the effect of BABA C is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

Shake the bottle well before use.

BABA C can be taken with or without food.

**If you give your child 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 centre.

Take this leaflet and the rest of the remaining BABA C with you so the doctor will know what you or your child have taken.

**4. Possible side effects**

BABA C can have side effects.

Not all side effects reported for BABA C are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking BABA C, please consult your healthcare provider for advice.

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

- swelling of your child's hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If your child has them, your child may have had a serious allergic reaction to BABA C and may need urgent medical attention or hospitalisation.

*Side effects occurring with an unknown frequency:*

- nausea (feeling sick), vomiting (being sick), diarrhoea (runny, loose stool).

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

**Reporting of side effects**

If your child gets side effects, talk to your doctor or pharmacist. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of BABA C.

## 5. How to store BABA C

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the bottle tightly closed.
- Do not use after the expiry date stated on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What BABA C contains

Each 5 ml contains:

The active substances are:

Ascorbic Acid (Vitamin C) .....	200 mg
Cholecalciferol (Vitamin D <sub>3</sub> ) .....	25 I.U.

The other ingredients are beta carotene (E160a), Blackcurrant NJ 0189/C flavourant, citric acid (E330), glucose (E1200), glycerine (E422), polyoxyl 40 hydrogenated castor oil, potassium sorbate (preservative) (E202), purified water, sodium benzoate (preservative) (E211), propylene glycol (E1520), sodium citrate (E331), sucrose (E473), xanthan gum (E415).

### What BABA C looks like and contents of the pack

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

100 ml amber, glass bottle with a white serrated, tamper-evident screw on cap, packed inside a carton.

### Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd

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Sunderland Ridge

Centurion

0157

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### This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

### Registration number

Will be allocated by SAHPRA upon registration.

### Access to the corresponding Professional Information

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

babsPIL-2K