

Tonicalcium®

Oral solution in ampoule

Adults : 10 ml snap-off ampoules

Children : 5 ml snap-off ampoules

IDENTIFICATION OF THE MEDICINAL PRODUCT

COMPOSITION 10 ml amp. 5 ml amp.

Calcium ascorbate 500 mg 250 mg

DL-lysine ascorbate 500 mg 250 mg

Excipients : propyl gallate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sorbitol, sucrose solution, glycerol, raspberry-redcurrant extract, purified water q.s.f. one ampoule.

Ascorbic acid (vitamine C) content : 362 mg per 5 ml ampoule and 724 mg per 10 ml ampoule. Alcohol content : 3.3°.

PHARMACEUTICAL FORM : Oral solution in ampoule.

Box of 20 x 5 ml ampoules (Children) or 10 ml (Adults).

PHARMACOTHERAPEUTIC GROUP

ANTI-ASTHENIC (A : gastrointestinal tract and metabolism)

NAME AND ADDRESS OF THE MARKETING COMPANY

BOUCHARA-RECORDATI Laboratories

68, rue Marjolin

92300 LEVALLOIS-PERRET-FRANCE

WHEN TO USE THIS MEDICINE ?

This medicine is indicated in the treatment of transitory fatigue in adults (10 ml amp.) or children over 6 years of age (5 ml amp.).

WARNING !

WHEN NOT TO USE THIS MEDICINE ?

This medicine *MUST NOT BE USED* in the following cases :

- history of allergy to one of the ingredients of the solution, particularly methyl or propyl parahydroxybenzoate;
- abnormally high calcium concentration in blood or urine;
- calcium deposits in the tissues;
- kidney stones [due to the presence of calcium and also during the use of high dose vitamin C (greater than 1 g)].

IF IN DOUBT, YOU MUST ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

PRECAUTIONS FOR USE

This medicine may cause insomnia; It must not be taken after 16h (4 p.m.). Take into account of the presence of calcium : 25.6 mg per 5 ml ampoule or 51.2 mg per 10 ml ampoule.

Patient on low sugar diet and those with diabetes should take the quantity of sucrose (sugar) into account in their daily food intake : 1.75 g per 5 ml ampoule or 3.5 g per 10 ml ampoule.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINES AND OTHER INTERACTIONS

TO PREVENT POSSIBLE INTERACTIONS BETWEEN DIFFERENT MEDICINES, ALWAYS INFORM YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER MEDICINE YOU ARE TAKING.

PREGNANCY AND BREAST-FEEDING

This medicine should preferably not be taken during pregnancy. If you discover that you are pregnant during the treatment, consult your doctor since he alone can evaluate the necessity for continuing with this treatment.

Use of this medicine should be avoided during breast-feeding.

IN GENERAL, IF YOU ARE PREGNANT OR BREAST-FEEDING, YOU SHOULD ALWAYS CONSULT YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINE.

LIST OF EXCIPIENTS WHICH NEED TO BE KNOWN FOR SAFE USE IN CERTAIN PATIENTS

Sucrose, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

HOW TO USE THIS MEDICINE ?

DOSAGE

10 ml ampoule : RESERVED FOR USE IN ADULTS.

2 ampoules per day.

5 ml ampoule : RESERVED FOR USE IN CHILDREN OVER 6.

2 ampoules per day.

THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU PERSONALLY IN SPECIFIC CIRCUMSTANCES :

- IT CAN NOT BE ADAPTED TO SUIT ANOTHER CASE.

- DO NOT RECOMMEND IT TO ANOTHER PERSON.

METHOD AND ROUTE OF ADMINISTRATION

Oral route.

Shake the ampoules before use. To be taken diluted in a little water.

Opening a snap-off ampoule : hold the ampoule upright and break the upper tip. Invert the ampoule over a glass, holding it on the slant so that the other tip is not over the glass.

Break this tip in the same way so that the liquid runs into the glass.

FREQUENCY AND TIME OF ADMINISTRATION

Avoid taking this medicine after 16h because of the presence of vitamin C.

DURING OF TREATMENT

Do not take for more than 4 weeks.

UNDESIRABLE AND UNPLEASANT EFFECTS

AS WITH ANY MEDICINE, THIS PRODUCT MAY PRODUCE UNPLEASANT EFFECTS OF VARYING SEVERITY IN SOME PEOPLE :

In some subjects, high doses of vitamin C (greater than 1 g) promote the formation of kidney stones and may increase haemolysis (destruction of the red blood cells) in subjects deficient in G6PG.

NOTIFY YOUR DOCTOR OR YOUR PHARMACIST OF ANY UNDESIRABLE OR UNPLEASANT EFFECT WHICH IS NOT MENTIONED IN THIS INFORMATION LEAFLET.

STORAGE

A slight deposit may appear in the ampoules and also slight excess pressure upon opening.

This does not indicate any change in the medicine and its activity is not in no way diminished. Shake before use.

DO NOT USE AFTER THE EXPIRY DATE STATED ON THE OUTER PACKAGING

SPECIAL STORAGE PRECAUTIONS : Keep protected from heat.

DATE OF REVISION OF THE INFORMATION LEAFLET :
September 2004.