

PATIENT INFORMATION LEAFLET (PIL)

AMINOCAL (Calcium, Vitamin D3, Vitamin B6, Lysine & Minerals tablets)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Aminocal is and what it is used for

Aminocal is a combination of Calcium, magnesium, pyridoxine hydrochloride, Cholecalciferol L-Lysine hydrochloride and Zinc tablet.

Aminocal is used for Calcium deficiencies during growth, pregnancy, breastfeeding.

Adjunctive treatment of osteoporosis: senile, post-menopausal, under corticosteroid therapy, immobilization during the resumption of mobility.

2. What you need to know before you take Aminocal

Do not take Aminocal:

- Hyper-sensitivity to one of the compounds.
- Hypercalcemia, hypercalciuria, calcium lithiasis, tissue calcification.
- Prolonged immobilization with hypercalcemia and / or
- hypercalciuria: calcium treatment should only be used when resumption of
- mobilization.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aminocal

- Joint administration of calcium and vitamin D should be done under monitoring of calcemia and calciuria.
- In case of renal insufficiency, regularly check for calcemia and calciuria, and avoid the administration of large doses.

Other medicines and Aminocal

- In case of treatment with digitalis: the oral administration of calcium, especially if it is associated with vitamin D, risking to increase the toxicity of digitalis, a strict clinical and electrocardiographic monitoring is necessary in case of association.
- In the case of treatment with oral tetracyclines: it is recommended to delay calcium intake for at least 3 hours (possible interference with the absorption of tetracyclines). When combined with vitamin D in high doses: weekly monitoring of calciuria and serum calcium is essential because of the risk of hypercalcemia.
- In the case of treatment with sodium fluoride or diphosphonates: it is advisable to take calcium away from sodium fluoride.
- If treated with thiazide diuretics: risk of hypercalcemia decreased urinary calcium elimination.

Pregnancy and breast-feeding

For Aminocal, no animal and clinical data are available. It is not known if this medicine can cause fetal malformations when administered during pregnancy or may affect fertility. Therefore, this drug should be given to pregnant women only if the potential benefits clearly outweigh the risks.

Calcium and magnesium are distributed in breast milk. Breastfeeding is not recommended during treatment with this medication.

Driving and using machines

Normally this medicine does not affect your ability to drive or operate machines.

Aminocal contains lactose

Aminocal does not contain Lactose.

3. How to take Aminocal

Recommend in adults only. Two tablets a day or as prescribed.

Method of Administration

Oral route. The tablets are swallowed with a large glass of water.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects or symptoms, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department.

Hypercalciuria in case of prolonged treatment at high doses, exceptionally hypercalcemia.

5. How to store Aminocal

Keep this medicine out of the sight and reach of children.

Store below 30°C. Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Aminocal film-coated tablets contain:

The **active substance** in Aminocal film-coated tablets is Calcium -400mg, Magnesium 90mg, Zinc 5mg, L-Lysine hydrochloride -100mg, Cholecalciferol 200IU, Pyridoxine hydrochloride 1.5mg

The other ingredients are:

Sodium Starch glycollate, Microcrystalline cellulose, Sodium bisulphate, Maize starch, Colloidal anhydrous silica, Methyl paraben, Propyl paraben, Purified water, Cellulose acetate phthalate, Brilliant blue lake, Acetone, Methylene chloride, Polysorbate 80, Butylated hydroxyl toluene, Cross carmellose sodium, Purified talc, Magnesium stearate, Hydroxy propyl methyl cellulose, Titanium dioxide, Propylene glycol, Isopropyl alcohol.

What Aminocal film-coated tablets look like and contents of the pack:

A dark blue coloured bolus shaped film coated tablet with a central notch on one side and plain on the other side.

Aminocal is supplied in the pack of:

10 tablets in Alu-PVC blister pack, such 3 blister are packed in a printed carton along with pack insert.

Marketing Authorisation Holder

M/S. TIL HEALTHCARE PVT LTD

Plot No: 100 West, R 5, South, Sri City, SEZ,
Cherivi Village, Irrugulam Post, Satyavedu Mandal,
Chittoor District-517588, Andhra Pradesh,
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