

Package Leaflet: Information for the user

Egostar 22 400 IU film-coated tablets

Cholecalciferol (Vitamin D3)

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Egostar is and what it is used for

Prevention of vitamin D deficiency in patients with an identified risk.

Initial treatment of clinically relevant vitamin D deficiency.

As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

Egostar is indicated in adults.

2. What you need to know before you take Egostar

Do not take Egostar

if you are allergic (hypersensitive) to cholecalciferol (vitamin D3), or any of the other ingredients of this medicine (listed in section 6);

if you have hypervitaminosis D (high levels of vitamin D in your blood);

if you have renal calculi (kidney stones) (nephrolithiasis);

severe renal problems (severe renal impairment);

if you have a disorder or condition resulting from high levels of calcium in your blood (hypercalcaemia) and/or urine (hypercalciuria).

Warnings and precautions

Talk to your doctor, or pharmacist or nurse before taking Egostar: if you have high levels of calcium in your blood (hypercalcaemia);

if you have renal impairment or renal calculi (kidney stones). Your doctor shall ask you to have regular blood tests to control the effect in the calcium and phosphate levels in your blood.

if you are taking medicines for your heart (e.g.: digitalis);

if you have been diagnosed to have a disease called sarcoidosis (a immune system disease, which can affect your liver, lungs, skin, or lymph nodes). Your doctor shall ask you to have regular blood tests to control the calcium levels in your blood and/or urine;

if you are already taking vitamin D, for example, through other medicines. the need to take additional calcium supplements shall be considered for specific patients. Calcium supplements should be given under close medical supervision; Medical supervision is required whilst on treatment to prevent the increase of calcium in your blood (hypercalcaemia). In the event of long-term treatment, calcium levels and the kidneys should be regularly monitored, in particular for elderly patients under treatment with medicinal products for the heart (e.g.: digitalis) or diuretics and in patients who have a tendency to form renal calculi (kidney stones).

Children

This medicinal product should not be given to children.

Other medicines and Egostar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is particularly important you tell your doctor or pharmacist if you:

- are taking vitamin A;
- are taking magnesium;
- are taking medicines for epilepsy (e.g., carbamazepine, phenobarbitol, phenytoin, and primidone);
- are taking medicines to treat tuberculosis (e.g. rifampicin, and isoniazid);
- are taking medicines for your heart (e.g., cardiac glycosides such as digitalis).

Your doctor should monitor your heart through an electrocardiogram (ECG) and control the calcium levels in your blood;
are taking corticosteroids;
are taking medicines to treat cancer (e.g., actinomycin) or anti-fungal medicines (e.g., benzimidazoles);
are taking medicines for the treatment of high blood pressure (thiazide diuretics);
are taking cholestyramine that is mainly used as a lipid lowering medicine or laxatives (e.g., paraffin oil);
are taking orlistat, indicated for the treatment of obesity.

Pregnancy, and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Egostar 22 400 IU tablets is not recommended in pregnancy. A low strength formulation should be used.

The daily recommended dose in pregnant women is 400 IU, however in women with vitamin D deficiency a higher dose may be required. During pregnancy, women should follow the medical recommendations as their vitamin D needs may vary according to the illness severity or the response to treatment.

Egostar 22 400 IU tablets is not recommended in breastfeeding women. A low strength formulation should be used.

Vitamin D and its metabolites are excreted in the human milk.

Driving and using machines

There are no data about the effect of this product on driving capacity. An effect is, however, unlikely.

Egostar contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Egostar contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially "sodium-free".

3. How to take Egostar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Tablets should be swallowed whole with water.
Patients should be advised to take Egostar preferably with a meal.

Use in adults

Dose should be established on an individual basis depending on the extent of the necessary vitamin D supplementation. The patient's dietary habits should be carefully evaluated and artificially added vitamin D content of certain food types should be taken into consideration.

Prevention of Vitamin D deficiency:

One tablet (22 400 IU) once every 28 days.

Initial treatment of Vitamin D deficiency:

One tablet (22 400 IU) once a week for four weeks. After four weeks, lower doses may be considered, dependent upon desirable serum levels of 25 hydroxycolecalciferol (25(OH)D), the severity of the disease and/or the patient's response to treatment.

As an adjunct to specific therapy for osteoporosis:

One tablet (22 400 IU) once every 28 days.

Treatment duration

The duration of treatment will depend on the indication, the severity of the disease and the response of the patient to treatment.

If you take more Egostar than you should

If you take more Egostar than you should, contact your doctor or the nearest hospital immediately. Acute or chronic overdose with vitamin D3 may increase the calcium levels in your blood. Vitamin D3 overdose requires treatment interruption and hydration, as well as measures to mitigate symptoms.

If you forget to take Egostar

Do not take a double dose to make up for a forgotten tablet.
Resume treatment as recommended by your doctor.

If you stop taking Egostar

If you stop treatment, you will put the treatment results at risk.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

4. Possible side effects

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

Side effects with Egostar may include, in rare cases, skin reactions such as itching, exanthema or rash.

With long-term administration of this medicinal product, calcium levels in your blood and urine may be increased.

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the HPRA via the contact bellows. By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Egostar

Keep this medicine out of reach and sight of children.

The product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton 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 Egostar contains

The active substance is cholecalciferol (vitamin D3). Each tablet contains 560 micrograms (22 400 IU) of cholecalciferol (vitamin D3).

The other ingredients are:

Core: sodium ascorbate; all-rac- α -tocopherol; modified starch; sucrose; medium chain triglycerides; silicon dioxide, colloidal; lactose monohydrate; povidone; crospovidone and sodium stearyl fumarate

Coating: Hypromellose; titanium dioxide (E171); macrogol 6000, talc

What Egostar looks like and contents of the pack

Egostar tablets are white, oblong, film coated and engraved with a "V3" mark on one of the sides of the tablet.

Egostar tablets are packed in PCTFE/PE.EVOH.PE/PVC/Alu opaque white blister

packs containing 1, 3 and 6 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Jaba Recordati, S. A.
Av. Jacques Delors
Ed. Inovação 1.2, Piso 0 - Taguspark
2740-122 Porto Salvo, Portugal

Manufacturer:

Atlantic Pharma – Produções Farmacêuticas, S.A.
Rua da Tapada Grande, n.º 2; Abrunheira, 2710-089 Sintra, Portugal

This leaflet was last revised in