

Patient Information Leaflet

(OSTOCALCIUM B₁₂ SUSPENSION)

Calcium (as Calcium Phosphate), Cholecalciferol (Vitamin D₃) and Vitamin B₁₂

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

What is in this leaflet

1. What *Ostocalcium B₁₂ suspension* is and what it is used for
2. What you need to know before you take *Ostocalcium B₁₂ suspension*
3. How to take *Ostocalcium B₁₂ suspension*
4. Possible side effects
5. How to store/ handle *Ostocalcium B₁₂ suspension*
6. Contents of the pack and other information

1. What Ostocalcium B₁₂ suspension is and what it is used for

This medicine contains three active substances Calcium, Vitamin D₃ and Vitamin B₁₂. It is used in the correction of combined Vitamin D₃, Calcium and Vitamin B₁₂ deficiencies

2. What you need to know before you take Ostocalcium B₁₂ suspension

Do not take *Ostocalcium B₁₂ suspension*

- If you are allergic to Calcium, vitamin D or any of the other ingredients of *Ostocalcium B₁₂ suspension*.
- If you have an abnormally high level of Calcium in the blood (hypercalcaemia) and/or excessive loss of Calcium in the urine (hypercalciuria).
- If you have a condition that could lead to hypercalcaemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumour (bone metastases).
- If you are suffering from kidney stones (nephrolithiasis) or have Calcium deposits in your kidneys (nephrocalcinosis).
- If you are suffering from an excessive supply of vitamin D (hypervitaminosis D)
- If you are suffering from kidney failure.

Warnings and precautions

Talk to your doctor before taking *Ostocalcium B₁₂ suspension*:

- In the case of long-term treatment with *Ostocalcium B₁₂ suspension*, the quantity of Calcium in the blood (calcaemia) must be regularly monitored. This monitoring is particularly important in older people and where treatment is being taken at the same time as cardiac glycosides (e.g. Digoxin) or diuretics. Depending upon the result, your doctor may decide to reduce or even stop your treatment.

Before taking *Ostocalcium B₁₂ suspension* tell your doctor:

- If you have had kidney stones.
- If you are suffering from an immune disorder (sarcoidosis), as the amount of Calcium in your blood and urine must be checked.
- If you are immobile and are suffering from reduced bone mass (osteoporosis). This may increase the level of Calcium in your blood too much which can cause side effects.
- If you are taking other medicines containing Vitamin D₃ or Calcium or Vitamin B₁₂. This may increase the level of Calcium in your blood too much which can cause side effects.
- If you are suffering from Leber's disease (hereditary optic nerve defect) or tobacco amblyopia (lazy eye) since these conditions may aggravate further due to Cyanocobalamin (Vitamin B₁₂)

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

- Phenytoin (a medicine for epilepsy) and barbiturates (medicines which help you sleep), as they may make the Vitamin D₃ less effective.
- Thiazide diuretics (medicines used to treat high blood pressure), as they may increase the amount of Calcium in your blood.
- Oral steroids, as they may reduce the amount of Calcium in your blood.
- Orlistat (a medicine used to treat obesity), Cholestyramine, laxatives such as paraffin oil, as they may reduce the amount of Vitamin D₃ you absorb.
- Tetracycline antibiotics, as the amount absorbed may be reduced. They should be taken at least two hours before, or four to six hours after *Ostocalcium B₁₂ suspension*.
- Quinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least two hours before, or four to six hours after *Ostocalcium B₁₂ suspension*.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much Calcium.
- Bisphosphonates (a treatment for bone conditions), as the amount absorbed may be reduced. They should be taken at least 1 hour before taking *Ostocalcium B₁₂ suspension*.
- Calcium may also reduce absorption of sodium fluoride and such preparations should be administered at least three hours before taking *Ostocalcium B₁₂ suspension*.
- In the two hours before taking *Ostocalcium B₁₂ suspension*, you should avoid eating foods containing oxalic acid (e.g. spinach and rhubarb) or phytic acid (e.g. wholegrain cereals), which can reduce Calcium absorption.

- Thyroid hormones, as the amount absorbed may be reduced. They should be taken atleast 2 hours before or after *Ostocalcium B₁₂ suspension*.
- Medicines containing iron, zinc or strontium, as the amount absorbed may be reduced.
They should be taken at least 2 hours before or after *Ostocalcium B₁₂ suspension*.
- Medicines, like, Omeprazole; Neomycin, if used orally may reduce the absorption of Vitamin B₁₂

Pregnancy and breast-feeding

- If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking any medicine.
- As Calcium and Vitamin D₃ passes into breast milk you have to check with your doctor first if your infant receives any other products containing Vitamin D₃.

Driving and using machines

- No effects on the ability to drive and use machines are expected.

3. How to take *Ostocalcium B₁₂ suspension*

- ADULTS: The daily dose is 2 to 4 teaspoonful (equivalent to 164-328 mg of elemental Calcium, 400-800 I.U. of Vitamin D and 5-10 mcg of Vitamin B₁₂), divided into 1 or 2 doses.
- CHILDREN: The daily dose for children are
 - o *For children below 1 year of age:* Please consult your doctor
 - o *For children above 1 year of age:* 1 to 2 teaspoonsful daily (equivalent to 82-164 mg of Calcium, 200-400 I.U. of Vitamin D and 2.5-5 mcg of Vitamin B₁₂) or as advised by the doctor.
- If you have taken more *Ostocalcium B₁₂ suspension* than you should have and experience any of the symptoms of overdose, stop taking *Ostocalcium B₁₂ suspension* and immediately contact your doctor. Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones. In the case of prolonged overdosage, Calcium deposits may appear in blood vessels or body tissues.

- 4. Possible side effects:** Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon side effect (affects 1 to 10 users in 1,000): excess Calcium levels in the blood or urine.

- Rare side effects (affects 1 to 10 users in 10,000): constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhea, itching, skin rashes and urticaria.
- Other side effects (frequency not known): kidney stones, vomiting (usually a symptom of overdose), allergic reactions including angioedema (sudden swelling of the face and neck with trouble breathing) and laryngeal edema (throat swelling and tightness).

5. How to store / handle Ostocalcium B₁₂ suspension

- Store in a well-closed container at temperature not exceeding 30°C. Protect from direct sunlight. Do not freeze.
- Keep out of reach of children.
- Shake the bottle before use.
- There are no other special requirements for use or handling of this product.
- Please see the expiry date as mentioned on the label & packaging

6. Contents of the pack and other information

- Each 5 ml (1 teaspoonful) contains:

Vitamin D ₃ (Cholecalciferol IP)	200 IU
Vitamin B ₁₂	2.5 mcg
Calcium Phosphate equivalent to elemental Calcium	82 mg
in a flavoured syrup base	
Colour: Erythrosine	

The other ingredients are: Sucrose, Phosphoric Acid, Calcium Hydroxide, Benzoic Acid, Sodium Methyl Hydroxybenzoate, Polysorbate 80, Propylene Glycol, Flavour Banana or Lemon lime, Sodium Hydroxide or Phosphoric acid.

- In a PET bottle.

- **DETAILS OF MANUFACTURER**
Naxpar Pharma Pvt. Ltd.,
182, Village - Gurumajra,
Kishanpura, Baddi, Dist. - Solan,

(H.P.) -174101

- MARKETED BY:
GlaxoSmithKline Asia Pvt. Ltd.
Patiala Road, Nabha – 147201 Punjab, India
- DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE
Manufacturing License Number: MB/07/618
- DATE OF REVISION
March 2022

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Reference PI: Version OSB/PI/IN/2020/01

Adapted from:

- *Calcium/cholecalciferol (CHEWCAL / OSTOCALCIUM / OSTOCALCIUM FORTE) NCDS Version 05 dated 21 Oct 2019.*
- *Vitamins and Minerals (VITAMAX) NCDS Version 05 dated 26 October 2018.*
- *PDR for Nutritional Supplements 2nd edition.*
- *Harrison's Principles of Internal Medicine 20th ed. Chapter 95 Megaloblastic Anemias)*

- CONSUMER CARE DETAILS:

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