

Package Leaflet: Information for the patient

DIBASE 100,000 IU/mL solution for injection DIBASE 300,000 IU/mL solution for injection

CHOLECALCIFEROL (VITAMIN D₃)

Read all of this leaflet carefully before you start using 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 DIBASE is and what it is used for
2. What you need to know before you use DIBASE
3. How to use DIBASE
4. Possible side effects
5. How to store DIBASE
6. Contents of the pack and other information

1. What DIBASE is and what it is used for

DIBASE contains cholecalciferol, which is better known as vitamin D₃. DIBASE is indicated for the prevention and treatment of Vitamin D deficiency.

2. What you need to know before you use DIBASE

Do not use DIBASE

- If you are allergic to cholecalciferol (vitamin D₃) or any of the other ingredients of this medicine (listed in section 6).
- If you have high calcium levels in blood (hypercalcaemia) or in urine (hypercalciuria).
- If you have kidney stones (nephrolithiasis) or calcium deposits in the kidneys (nephrocalcinosis).
- If you have a kidney disease (renal insufficiency) (see section "Warnings and precautions").

Warnings and precautions

Talk to your doctor or pharmacist before taking DIBASE.

The doctor might recommend taking DIBASE as **prevention against Vitamin D deficiency**:

- for neonates (especially preterm babies) and infants;
- during the last trimester of pregnancy;
- for breastfeeding women, late in winter and in spring;
- for the elderly;
- in case of inadequate exposure to sunlight, particularly in the child and the adolescent;
- in case of an unbalanced diet (e.g., poor in calcium, vegetarian diet);
- in case of intense skin colouration;
- in case of extensive skin diseases, infectious diseases (e.g., tuberculosis, leprosy), digestive diseases or liver diseases (hepatic insufficiency);
- in patients under treatment with antiepileptic medicines or under long-term therapy with certain anti-inflammatory agents.

The doctor might prescribe regular tests to check the levels of vitamin D or calcium in blood and urine in the following cases:

- if you need to take DIBASE for a prolonged period and at high doses;
- if you are elderly and already under treatment with medicines for certain heart diseases (cardiac glycosides) or with medicines that reduce blood pressure by increasing the production of urine (diuretics);
- if you have sarcoidosis, an inflammatory disease that can involve the entire body and lead to the formation of nodules;
- if you have high levels of vitamin D or calcium, your doctor will reduce the dose or suspend treatment with DIBASE.

Generally, you should not take DIBASE if you have scarce kidney function (see section "Do not use DIBASE"); but if the doctor deems that treatment with DIBASE is absolutely necessary, you will need to perform regular tests to check blood levels of calcium and phosphate. If your calcium and phosphate levels are high, your doctor will reduce the dose or interrupt treatment with DIBASE.

Inform the doctor in the following cases because it might be necessary to increase the doses, compared to the ones indicated in section 3 "How to use DIBASE":

- if you are taking medicines that are used to treat seizures (anticonvulsants or barbiturates) (see section "Other medicines and DIBASE");
- if you are taking cortisone, medicines that are used to treat inflammation (see section "Other medicines and DIBASE");
- if you are taking medicines that are used to reduce the presence of fatty acids in the blood, such as cholestipol, cholestyramine and orlistat (see section "Other medicines and DIBASE");

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- if you are taking antacids that contain aluminium, medicines that are used to treat the excessive presence of acid in the stomach, which can even enter the oesophagus (see section "Other medicines and DIBASE");
- if you are obese;
- if you have digestive diseases (intestinal malabsorption, mucoviscidosis or cystic fibrosis);
- if you have a liver disease (hepatic insufficiency).

Other medicines and DIBASE

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

Particularly, tell your doctor if you are taking the following medicines because they might reduce the effect of DIBASE:

- medicines that are used to treat seizures (anticonvulsants or barbiturates);
- medicines that are used to reduce the presence of fatty acids in the blood, such as cholestipol, cholestyramine and orlistat;
- if you are taking antacids that contain aluminium, medicines that are used to treat the excessive presence of acid in the stomach, which can even enter the oesophagus;
- cortisone, medicines that are used to treat inflammation.

Moreover, if you are taking the following medicines, tell your doctor, who will monitor your condition and carefully evaluate whether you need to perform additional tests:

- thiazide diuretics, medicines that are used to treat high blood pressure by increasing the production of urine;
- digitalis, medicine that is used to treat certain heart diseases;
- preparations that contain magnesium;
- warfarin, medicine that is used to make blood more fluid.

DIBASE with food, drink and alcohol

Tell your doctor if you are taking other products that already contain vitamin D, foods fortified with vitamin D or if you use milk enriched with vitamin D so that he might consider the total dose of vitamin D you are taking to avoid an excessive dose (see section "Warnings and precautions").

The intake of high amounts of alcohol for a very long time (chronic alcoholism) reduces vitamin D reserves in the liver.

Pregnancy and breastfeeding

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

Pregnancy

During the first 6 months of pregnancy, the doctor will prescribe this medicine only if he deems it strictly necessary, due to the risk of harmful effects for the foetus. (See Section 3 "If you use more DIBASE than you should")

Breastfeeding

The doctor will prescribe this medicine during breastfeeding, when necessary. This does not substitute the administration of vitamin D to the neonate.

Driving and using machines

It is unlikely that DIBASE will have any effects on the ability to drive vehicles.

How to use DIBASE

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

The doses and duration of treatment will be evaluated by the doctor, based on your health conditions.

Do not exceed the doses indicated by the doctor.

Doses can be taken either orally or by intramuscular injection.

In case of oral administration, it is recommended to take DIBASE during meals.

Intramuscular therapy is indicated only for malabsorption syndromes.

DIBASE 100,000 IU/mL solution for injection

Neonates and children up to 2 years of age

Prevention: you are recommended to take DIBASE 10,000 IU/mL oral drops, solution or DIBASE 25,000 IU/2.5 mL oral solution or DIBASE 50,000 IU/2.5 mL oral solution.

Treatment: the recommended dose is 1 ampoule (equal to 100,000 IU of vitamin D₃) once a month for 4-6 months.

Children and adolescents (2-18 years)

Prevention: the recommended dose is 1 ampoule (equal to 100,000 IU of vitamin D₃) every 4-8 months.

Treatment: the recommended dose is 1 ampoule (equal to 100,000 IU of vitamin D₃) once a month for 4-6 months.

Use in pregnant women

The recommended dose is 1 ampoule (equal to 100,000 IU of vitamin D₃) at the start of the last trimester.

Adults and the elderly

Prevention: the recommended dose is 1 ampoule (equal to 100,000 IU of vitamin D₃) every 4 months.

In case of a high risk of deficiency, the doctor will assess whether you need to increase the dose to 1 ampoule (equal to 100,000 IU of vitamin D₃) every 2 months.

Treatment: the recommended dose is 2 ampoules (equal to 200,000 IU of vitamin D₃) once a month for 3 months.

DIBASE 300,000 IU/mL solution for injection

Neonates and babies up to 2 years of age

You are recommended to take DIBASE 10,000 IU/mL oral drops, solution or DIBASE 25,000 IU/2.5 mL oral solution or DIBASE 50,000 IU/2.5 mL oral solution.

Children and adolescents (2-18 years)

Prevention: the recommended dose is 1 ampoule (equal to 300,000 IU of vitamin D₃) once a year.

Treatment: the recommended dose is 1 ampoule (equal to 300,000 IU of vitamin D₃) to be repeated after 3 months.

Adults and the elderly

Prevention: the recommended dose is 1 ampoule (equal to 300,000 IU of vitamin D₃) once a year. In case of a high risk of deficiency, the doctor will assess whether you need to increase the dose to 1 ampoule (equal to 300,000 IU of vitamin D₃) every 6 months.

Treatment: the recommended dose is 1 ampoule (equal to 300,000 IU of vitamin D₃) to be repeated after 6 weeks.

Instructions for use

The ampoules contained in the package have a pre-scored ring. Follow the instructions for use given below:

- a. hold the bottom of the ampoule with one hand;
- b. place the other hand on the top part positioning the thumb on the white ring;
- c. apply pressure.

If you use more DIBASE than you should

In case of accidental ingestion/intake of an overdose of DIBASE, immediately inform the doctor or visit the closest hospital.

In case of overdose there might be an increase in the levels of calcium in blood and urine, with the following symptoms: nausea, vomiting, thirst, intense thirst (polydipsia), increased quantity of urine excreted (polyuria), constipation and dehydration.

Chronic overdose can cause build-up of calcium salts in blood vessels and organs.

The use of an excessive dose of vitamin D during the first 6 months of pregnancy can cause serious harm to the foetus and to the neonate.

If you forget to use DIBASE

Do not use a double dose to make up for the forgotten dose.

If you stop using DIBASE

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

4. Possible side effects

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

The side effects reported with the use of vitamin D are listed below:

- allergic reactions;
- weakness, loss of appetite (anorexia), thirst;
- drowsiness, confusion;
- headache;
- constipation, emission of gas (flatulence), stomach pain, nausea, vomiting, diarrhoea, metallic taste, dry mouth;
- rash, pruritus;
- excessive build-up of calcium in the kidneys (nephrocalcinosis), increased quantity of urine excreted (polyuria), intense thirst (polydipsia), kidney disease (renal insufficiency)
- high calcium levels in blood (hypercalcaemia) and in urine (hypercalciuria).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store DIBASE

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

Do not use this medicine after the expiry date which is stated on the 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.

Do not store above 30°C. Do not freeze.

Store in the original package in order to protect from light.

6. Contents of the pack and other information

What DIBASE contains

DIBASE 100,000 IU/mL solution for injection

- The active substance is cholecalciferol (vitamin D₃) (one ampoule contains 2.5 mg equal to 100,000 I.U.)
- The other ingredient is refined olive oil for injection.

DIBASE 300,000 IU/mL solution for injection

- The active substance is cholecalciferol (vitamin D₃) (one ampoule contains 7.5 mg, equal to 300,000 IU)
- The other ingredient is refined olive oil for injection.

Description of the aspect of DIBASE and the package contents

DIBASE is presented as a solution contained in an amber-coloured glass ampoule with pre-scored ring.

DIBASE 100,000 IU/mL solution for injection

Available in packages containing 1 ampoule, 3 ampoules or 6 ampoules, 100,000 IU/mL each.

DIBASE 300,000 IU/mL solution for injection

Available in packages containing 1 ampoule or 2 ampoules, 300,000 IU/mL each.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

ABIOGEN PHARMA S.p.A. - Via Meucci, 36, Ospedaletto – Pisa - ITALY

This leaflet was last revised in:

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