

Package leaflet: Information for the patient

Plenachol® D₃ 20 000 IU Capsules & Plenachol® D₃ 40 000 IU Capsules (Colecalciferol)

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.
- The full name of this medicine is Plenachol® D₃ 20 000 IU Capsules and Plenachol® D₃ 40 000 IU Capsules but within the leaflet it will be referred to as Plenachol Capsules.

- What is in this leaflet:**
1. What Plenachol Capsules are and what they are used for
 2. What you need to know before you take Plenachol Capsules
 3. How to take Plenachol Capsules
 4. Possible side effects
 5. How to store Plenachol Capsules
 6. Contents of the pack and other information

1. What Plenachol Capsules are and what they are used for

Plenachol Capsules contain the active ingredient colecalciferol (also known as vitamin D₃). Vitamin D is required in the body to help in the absorption of calcium. Vitamin D can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D helps the kidneys and intestine absorb calcium which helps build bones.

Plenachol Capsules are used:

- For the prevention of vitamin D deficiency when there is a significant risk of deficiency or an increased demand for vitamin D.
- For the treatment of vitamin D deficiency that has been confirmed by laboratory tests.
- With other medicines to treat certain bone conditions, such as thinning of the bone (osteoporosis).

2. What you need to know before you take Plenachol Capsules

Do not take Plenachol Capsules:

- If you are allergic to colecalciferol or any of the ingredients of this medicine (listed in section 6).
- If you have raised levels of calcium in your blood (hypercalcaemia) and/or raised levels of calcium in your urine (hypercalcuria).
- If you have severe kidney problems.
- If you have a tendency to form calcium containing kidney stones.
- If you have high levels of vitamin D in your blood (hypervitaminosis).



Warnings and precautions

Talk to your doctor or pharmacist before taking Plenachol Capsules if you:

- Are undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides, such as digoxin).
- Have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body).
- Are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D.
- Are likely to be exposed to a lot of sunshine whilst taking Plenachol Capsules.
- Take additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are taking Plenachol Capsules.
- Have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Plenachol Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Taking some medicines together can be harmful.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethiazide). When used at the same time as vitamin D these medicines may cause a large increase in the level of calcium in the blood and urine.
- Medicines containing vitamin D or eating food rich in vitamin D, such as some types of vitamin D-enriched milk.
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes vitamin D.

- The following medicines because they can interfere with the effect or the absorption of vitamin D:
 - Antiepileptic medicines (such as phenytoin) or medicines to treat sleep disorders and epilepsy (barbiturates such as phenobarbitone).
 - Glucocorticoids (steroid hormones such as hydrocortisone and prednisolone). These can decrease the effect of vitamin D.
 - Medicines that lower the level of cholesterol in the blood (such as cholestyramine or colestipol).
 - Certain medicines for weight loss that reduce the amount of fat your body absorbs (such as orlistat).
 - Certain laxatives (such as liquid paraffin).

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

Plenachol Capsules with food and drink

You should take this medicine preferably together with a large meal to help your body absorb the vitamin D.

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 or pharmacist for advice before taking this medicine.

This high strength formulation is not recommended for use in pregnant and breast feeding women.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or use heavy machinery.

3. How to take Plenachol Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Plenachol Capsules should be taken orally.

Swallow the capsules whole (not chewed) with a drink of water. You should take Plenachol Capsules preferably together with a large meal.

The recommended dose is:

Adults

- Prevention of vitamin D deficiency: 20,000 IU once a month
- Treatment of vitamin D deficiency: 40,000 IU once a week for 7 weeks, followed by maintenance therapy, (equivalent to 1,400-2,000 IU a day, such as two to three 20,000 IU capsules per month), based on the advice of your doctor.

Use in children and adolescents

- Prevention of vitamin D deficiency 12-18 years: 20,000 IU every 6 weeks
- Treatment of vitamin D deficiency 12-18 years: 20,000 IU once every 2 weeks for 6 weeks

Plenachol Capsules are **not suitable for children under 12 years.**

The doctor must decide on an individual basis whether any further treatment (follow-on or long-term) with Plenachol Capsules is necessary.

During long-term treatment, the calcium levels in the blood and urine should be monitored regularly and kidney function tested by measurement of serum creatinine. If necessary, the dosage must be adjusted according to the blood calcium values (see Section 2 Warnings and precautions).

If you take more Plenachol Capsules than you should:

If you accidentally take too many capsules, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicine or the empty packet to the doctor.

An overdose can lead to increased levels of calcium in the blood (hypercalcaemia) and in the urine (hypercalciuria), shown by lab tests.

Signs and symptoms of an overdose can be nausea (feeling sick), vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration.

Your doctor will treat you accordingly in case of an overdose.

If you forget to take Plenachol Capsules:

Do not worry. If you miss a dose, take another as soon as you remember, unless it is almost time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

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 have side effects, although not everybody gets them. Possible side effects may include:

Uncommon (may affect up to 1 in 100 people):

- Too much calcium in your blood (hypercalcaemia)
- Too much calcium in your urine (hypercalciuria)

Rare (may affect up to 1 in 1,000 people):

- Skin rash
- Itching
- Hives

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.



5. How to store Plenachol Capsules

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

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

Do not take this medicine after the expiry date on the carton and blister as [EXP XX/YYYY]. 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 Plenachol Capsules contain:

The active substance is colecalciferol (also known as vitamin D₃).

Each Plenachol 20 000 IU Capsule contains colecalciferol equivalent to 0.5 mg of vitamin D₃.

Each Plenachol 40 000 IU Capsule contains colecalciferol equivalent to 1.0 mg of vitamin D₃.

The other ingredients are: medium-chain triglycerides, butylhydroxyanisole, colloidal anhydrous silica and hypromellose.

The capsule shell contains hypromellose and titanium dioxide (E171).

What Plenachol Capsules look like and contents of the pack:

Plenachol Capsules are hard white capsules containing a clear, slightly yellowish oily liquid.

Plenachol 20 000 IU Capsules are available in boxes of 4, 10 & 20 capsules.

Plenachol 40 000 IU Capsules are available in boxes of 4, 7, 10 & 20 capsules.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom

Manufacturers:

MW Encap Limited, Building 1, Units 2-8, Oakbank Park Way, Oakbank Industrial Estate, Mid Calder, Livingston, EH53 0TH, United Kingdom

Wasdell Packaging Limited

Units 1, 2, 3, 5, 6, 7 & 8 Euroway Industrial Estate, Blagrove, Swindon, SN5 8YW, United Kingdom

This leaflet was last revised in July 2020.

If you would like a leaflet with larger text, please contact 01271 385257.