Package Leaflet: Information for the user

Dropivit 20.000 IE/ml druppels voor oraal gebruik, oplossing
cholecalciferol (vitamine D_3)

Read 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.

What is in this leaflet:

1. What <invented name> drops are and what they are used for

<invented name> drops contain vitamin D.

Vitamin D increases the absorption of calcium from the bowel system, the reabsorption of calcium in the kidneys and bone formation, and decreases the level of parathormone (PTH). In addition to the skeletal system, vitamin D receptors are present in numerous other tissue types, and that is exactly why vitamin D has diverse actions in various physiological processes.

<invented name> drops may be used in the following cases:
- to treat vitamin D deficiency in adults and adolescents
- to prevent vitamin D deficiency in adults and adolescents with an identified risk
- with other medicine to treat thinning of the bone (osteoporosis) in adults.

2. What you need to know before you take <invented name> drops

Do not take <invented name> drops in the following cases:
- if you are allergic to vitamin D or to any other ingredient of the medicine listed in Section 6,
- if you have high blood levels of calcium (hypercalcemia) and/or high urine levels of calcium (hypercalciuria),
- if you have kidney stones
- if you are known with/have calcifications in your kidneys
- if you have high levels of vitamin D in the blood (hypervitaminosis D)

Warnings and precautions
Talk to your doctor or pharmacist before you start taking <invented name> drops:
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other drugs containing vitamin D.
- if you have Pseudohypoparathyroidism (a hereditary disorder causing problems with the

parathyroid hormone levels
- if you have kidney problems or have had kidney stones.

Your doctor may want you to have regular blood and urine tests to check the amount of calcium and phosphate in your blood.

Other medicines and <invented name> drops
You must tell your doctor or pharmacist if you are taking, have recently taken or are planning to take any other medicines.

Tell your doctor if you are taking any of the following medicines:
- thiazide type diuretics (water pills) – they reduce the excretion of calcium into the urine;
- corticosteroids (medicines for decreasing inflammation and for the treatment of immune disorders and asthma) – they prevent the absorption of calcium;
- ion-exchange resins (such as cholestyramine, colestipol) or laxatives (such as paraffin oil) – they reduce the absorption of vitamin D;
- orlistat – it may decrease the absorption of fat-soluble vitamins, including vitamin D;
- magnesium-containing products (such as antacids)
- heart glycosides, also called digitalis medicines (for the treatment of heart failure and certain heart diseases) – the risk of digitalis overdose is higher;
- anticonvulsive medicines (for the treatment of epilepsy), phenytoin or other barbiturates – they may reduce the effect of vitamin D;
- phosphorus-containing products at high doses – they increase the risk of development of high blood levels of phosphate (hyperphosphatemia);

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, or if you may be pregnant or are planning to have a child, talk to your doctor or pharmacist before you start taking this medicine.

Adequate vitamin D intake is required during pregnancy and breast-feeding.

Pregnancy
You should not take this medicine during pregnancy without a confirmed vitamin D deficiency and your doctor finds it absolutely necessary for you.

<invented name> passes into breast milk. Your doctor may need to adjust the dose if your child is receiving additional Vitamin D.

Driving and using machines
<Invented name> has no or negligible influence on the ability to drive and use machines.

3. How to take <invented name> drops

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure about the dosage.
Individually tailored dosage is required; the dosage depends on the necessary extent of vitamin D supplementation and on the type of illness for which your doctor has prescribed <invented name> drops for you.

<u>Initial treatment of vitamin D deficiency:</u>
The recommended dose is 2 to 8 drops every day (equivalent to 1000-4000 IU/day).

<u>Prevention of vitamin D deficiency in adults with an identified risk:</u>
The recommended dose is 1 or 2 drops every day (equivalent to 500-1000 IU/day).

<u>When used with other medicine to treat thinning of the bone (osteoporosis) in adults:</u>
The recommended dose is 2 drops every day (equivalent to 1000 IU/day).

Use in children
<invented name> is not recommended in children under 12 years of age.

Adolescents
Initial treatment of vitamin D deficiency:
The recommended dose is 2 drops every day (equivalent to 1000 IU/day).

Prevention of vitamin D deficiency with an identified risk:
The recommended dose is 1 or 2 drops every day (equivalent to 500-1000 IU/day).

Method and duration of administration:
Adolescents and adults should take <invented name> drops with a teaspoonful of liquid.

The bottle containing the medicine should be held upside down, in a vertical position. It may take some time for the first drop to appear.

If you take more <invented name> drops than you should
<invented name> drops are readily absorbed even at high doses. Acute or chronic overdose of vitamin D_3 may cause hypervitaminosis resulting the elevation of the blood levels of calcium, which may be prolonged and life-threatening. In extreme cases elevation of the blood levels of calcium may lead to coma or death. The symptoms are not markedly characteristic and obvious, and they may include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, increased urination, dehydration, kidney stone formation, kidney calcification, heart rhythm problems, muscle weakness, tiredness, confusion. Furthermore, chronic overdose may lead to calcification in tissues outside the skeleton as well as irreversible kidney damage.

In case of actual or suspected overdose, you must ask for medical help at once, and hospital treatment may also become necessary.

If you forget to take <invented name> drops
If you forgot to take <invented name> drops, wait for the time of the next dose, and continue the administration of the medicine as prescribed by your doctor. Do not take a double dose to make up for a missed dose. If you have not taken the medicine for several days, contact your doctor.

If you stop taking <invented name> drops
If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking <invented name> and seek immediate medicinal help if you experience symptoms of serious allergic reactions, such as:
- swollen face, lips, tongue or throat
- difficult to swallow
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): Too much calcium in your blood (hypercalcemia).

Rare (may affect up to 1 in 1,000 people): itching, skin rash and hives.

Not known (frequency cannot be estimated from the available data): constipation, flatulence, nausea, abdominal pain, diarrhea.

Reporting of side effects
If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not

listed in this leaflet. You can also report side effects directly to the authority via the contact details listed in Annex V. By reporting side effects, you can help provide more information on the safety of the use of this medicine.

5. How to store <invented name> drops

This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

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

Do not use this medicine after the expiry date (Use by:/EXP:) stated on the bottle. The expiry date refers to the last day of the stated month.

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

6. Contents of the pack and other information

What <invented name> drops contain
- The active ingredient of the medicine is cholecalciferol (vitamin D_3).
  1 ml solution (40 drops) contains 0.5 mg cholecalciferol, which quantity is equivalent to 20,000 IU (international units) of vitamin D_3.
  1 drop is equivalent to 500 IU vitamin D_3.
- Other ingredients: medium chain triglycerides.

What <invented name> drops look like, and contents of the pack
Transparent, slightly yellowish, viscous solution.
10 ml solution filled into type III brown glass bottle closed with HDPE screw cap fitted with LDPE dropper, placed into cardboard box.

Marketing Authorization Holder and Manufacturer

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In het register ingeschreven onder RVG 130323

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland: Dropivit 20.000 IE/ml druppels voor oraal gebruik, oplossing
Tsjechië: VITAMIN D3 AXONIA

Slowakije: VITAMIN D3 AXONIA 20 000 IU/ml perorálne roztokové kvapky

Deze bijsluiter is voor het laatst goedgekeurd in: maart 2024