

PACKAGE LEAFLET: Information for the patient

ADVIT

Oral drops solution – (10.000 UI + 10.000 UI) / ml
(Vitamin A + Vitamin D)

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Advit is and what it is used for
2. Before you take Advit
3. How to take Advit
4. Possible side effects
5. How to store Advit
6. Other information

1. WHAT ADVIT IS AND WHAT IT IS USED FOR

Advit contains the active substances vitamin A (retinol) and vitamin D (ergocalciferol). Vitamin A is essential for retinal rhodopsin regeneration, for the normal epithelium formation and for the growth. Vitamin A insufficiency can cause blindness, hyperkeratosis and metaplasia of the mucosa, which becomes more vulnerable to infections. Vitamin D regulates the normal metabolism of calcium and phosphorus and prevents and treats rickets. Vitamins A and D are fat soluble vitamins. They are absorbed from the digestive system to an extent of about 80%, whereas the absorption of higher doses is lower. Absorption depends from bile salts. Advit is used for the prevention and treatment of vitamin A and D insufficiency.

2. BEFORE YOU TAKE ADVIT

Do not take Advit:

- if you are hypersensitive to vitamins A and D or to any of the excipients of Advit;
- if you have hypercalcemia.

Take special care with Advit

Ask your doctor before you take Advit.

To prevent vitamin A and D overdoses, it should be kept in mind the amount of these vitamins that babies receive with breast milk or special milk for children. 100 mL of human milk contains 200 UI of vitamin A and 10 UI of vitamin D. The same amount of cow milk contains 80 UI of vitamin A and 10 UI of vitamin D. Different types of special milk for children contain different amounts of these vitamins. The amount of these vitamins is indicated in special sheets that accompany the prepared milk for babies.

Vitamin A should be used with caution in patients with liver disease. It should be used with caution in infants, which may be more sensitive to its effects, in patients with damaged renal system, or with heart disease and in patients who can have organ damage in case of hypercalcemia.

During vitamin D therapy, the plasmatic concentration of phosphates should be monitored, to avoid the danger of ectopic calcification. Also, patients receiving pharmacological doses of vitamin D, should monitor plasmatic calcium concentration at regular intervals, especially at the beginning of treatment and in the case of a suspected toxicity.

Infants, should be monitored if they are being breastfed by mothers who receive pharmacological doses of vitamin D.

Taking other medicines

- Neomycin, bleomycin, colestyramine and liquid paraffin can markedly reduce the absorption of vitamin A.
- If acitretin, tretinoin or isotretinoin are given simultaneously with vitamin A, a condition similar to vitamin A overdosage may occur.
- Heavy consumption of alcohol may increase betacarotene levels and affect vitamin A metabolism.

- Patients who are given concomitantly high doses of vitamin D and diuretics (such as the thiazides, which can reduce the urinary excretion of calcium), can develop hypercalcaemia and possibly metabolic alkalosis.
- The long-term use of phenytoin, phenobarbital, or primidone can disturb vitamin D and calcium metabolism and may result in osteomalacia.
- Rifampicin and isoniazid can reduce the effect of vitamin D.

Pregnancy and breastfeeding

Ask your pharmacist or doctor before taking this medicine.

Vitamins A and D cross the placenta and are excreted with breast milk. Because of the teratogenic and toxic potential that these vitamins present if taken in high doses, they can be used only with medical advice.

Driving and using machines

No effect has been observed on the ability to drive and use machines.

3. HOW TO TAKE ADVIT

Always take Advit exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage of Advit is individual.

The daily dosage recommended for children is as follows:

- up to 1 year: 5 drops;
- 2 - 5 years: 5 - 10 drops;
- 6 - 12 years: 5 - 10 drops.

After 14 days, a break of 1 - 2 weeks is recommended.

The drops are used immediately before meals, alone or with a teaspoon of milk. If the food contains insufficient amounts of proteins and fat, vitamin A requirements grow. Babies born prematurely and babies with digestive disorders (malabsorption syndrome) need higher doses.

The daily dosage for adults is:

- 10 – 20 drops 1 – 2 times daily.

1 drop of ADVIT = 250 UI of vitamin A and 250 UI of vitamin D.

If you have taken more Advit

If you have taken more Advit than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for actions to be taken.

If you forget to take Advit

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Advit can cause side effects, although not everybody manifests them. Most of the side effects are dose related and disappear when the dose is reduced or the treatment is interrupted. Some side effects can happen at the beginning of the treatment and disappear spontaneously with treatment continuance.

At recommended doses, practically there is no risk of side effects. As a result of overdoses, hypervitaminosis may appear. Hypervitaminosis initial signs are: tense fontanelle, thirst, polyuria, nausea, anorexia, vomiting, skin drying, removal of the skin of the palms of the hands and soles of the feet in form of scales, itching, bone and joints pain. There is also the possibility of hypersensitivity reactions, but they are very rare. Treatment should be discontinued if signs of hypervitaminosis or hypersensitivity reactions appear.

5. HOW TO STORE ADVIT

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

Store below temperature 25°C.

Do not use Advit after the expiry date, which is stated on the package.

Keep in the original packaging to protect it from light and humidity.

6. OTHER INFORMATION**What Advit contains**

The active substances are vitamin A (retinol) and vitamin D (ergocalciferol).

1 ml of oral drops solution contains 10,000 UI vitamin A and 10,000 UI vitamin D.

The excipients are: butylated hydroxytoluene, butylhydroxyanisole, refined olive oil.

Content of the pack: carton box with one plastic bottle of 20 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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