

PACKAGE LEAFLET: Information for the patient

VITAMINE E

Sugar-coated tablets – 10 mg

(Alpha-tocopherol acetate)

Read all of 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. What Vitamine E is and what it is used for
2. What you need to know before you take Vitamine E
3. How to take Vitamine E
4. Possible side effects
5. How to store Vitamine E
6. Other information

1. WHAT VITAMINE E IS AND WHAT IT IS USED FOR

Vitamin E is a fat-soluble vitamin.

Vitamin E prevents the oxidation of polyunsaturated fatty acids. It reacts with free radicals, which are the cause of oxidative damage to cell membranes.

Vitamin E deficiency is rare but develops when the dietary intake is inadequate. In children with congenital disorders such as cystic fibrosis or biliary atresia, malabsorption of fat may lead to vitamin E deficiency; deficiency may also occur in children with abnormalities of lipid transport, as in abetalipoproteinemia. Low vitamin E concentrations are also found in premature or very

low birth-weight infants. The major signs of vitamin E deficiency are myopathic and neurological disorders.

Vitamin E is indicated in:

- prevention and treatment of vitamin E deficiency developing as a result of malabsorption caused by cystic fibrosis, chronic cholestasis and abetalipoproteinemia.

Other indications include risk of abortion or risk of premature birth, several menstrual cycle disorders, oligospermia, asthenospermia, male sterility, myopathy, nocturnal enuresis, neurotonic asthenic syndrome, primary muscular dystrophy; also it is used as adjuvant treatment in several endocrine disorders such as hypogonadism, thyrotoxicosis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VITAMINE E

Do not take Vitamine E:

- if you are allergic to alpha-tocopherol acetate or to any of the excipients of this medicine.

Take special care with Vitamine E

Talk to your doctor before taking Vitamine E.

There is evidence that Vitamin E increases the risk of thrombosis in predisposed patients, including those who use estrogen such as women who use oral contraceptives that contain estrogens.

In preterm neonates with a low birth weight (less than 1.5 kg) treated with vitamin E, a higher incidence of necrotising enterocolitis has been noticed.

High doses of tocopherol acetate should not be used during pregnancy, especially during the first trimester.

Other medicines and Vitamine E

The concomitant use of other medicines could influence the effect of Vitamine E or the other medicine's effect.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines without prescription. Inform your doctor that you are taking Vitamine E if any other medicine is prescribed to you during treatment.

It is particularly important that your doctor knows that you are taking the following medicines:

- vitamin K, because vitamin E may antagonise its effect and thus increase coagulation time in predisposed patients. It has also been suggested that it may increase the risk of thrombosis in some patients, such as those taking estrogens. However, clinical significance of these effects is not known;
- coumarin anticoagulants, because vitamin E possibly enhances their anticoagulant effects;
- tipranavir, increased risk of bleeding when high doses of vitamin E are given with tipranavir;
- cyclosporin, because vitamin E possibly affects its plasma concentrations.

Taking Vitamine E with food and drinks

No available data.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking this medicine.

Vitamin E is poorly transferred across the placenta, but should not be used in large doses during pregnancy, particularly during the first trimester.

Vitamin E appears in breast milk. Caution is advised.

Driving and using machines

No available data.

Important information about some of the excipients of Vitamine E

This medicine contains lactose and sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

The sugar-coated tablets contain AZO colouring agents, as sunset Yellow FCF (E 110) and ponceau 4R (E 124) which may cause allergic reactions.

This drug contains sodium benzoate.

3. HOW TO TAKE VITAMINE E

Always take Vitamine E exactly as your doctor has told you. Check with your doctor if you are not sure or if you feel that the effect of Vitamine E is too strong or too weak.

The recommended doses are as follows:

Adults:

- malabsorption disorders, the following doses are used: cystic fibrosis: 100 – 200 mg daily, in divided doses; abetalipoproteinemia: 50 – 100 mg / kg daily, in divided doses;
- other disorders such as risk of abortion, male sterility, prevention of fetus development disorders: 100 – 300 mg daily;
- amenorrhea, oligomenorrhea, hypomenorrhea: 300 – 400 mg daily for 5 consecutive days during the second half of the menstrual cycle;
- blood vessel injuries: 50 – 100 mg daily.

Children:

- malabsorption disorders: children under 1 year of age 50 mg daily; children above 1 year of age 100 mg daily;
- abetalipoproteinemia: 50 – 100 mg/kg daily;
- in chronic cholestasis: 150 mg – 200 mg/kg daily.

However, it may be necessary that your dose be increased or lowered. Your doctor will recommend a dose after evaluating your clinical condition.

If you take more Vitamine E than you should

If you take more Vitamine E than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on actions that should be taken.

If you forget to take Vitamine E

If you forget to take one or more doses, take the next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Sometimes they may be serious and sometimes not.

Side effects may develop with large doses; those are diarrhea and abdominal pain.

If any of these side effects gets worse or if you get any side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE VITAMINE E

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 package.

Do not store above 25°C.

Keep in the original packaging.

6. OTHER INFORMATION

What Vitamine E contains

The active substance is alpha-tocopherol acetate.

Each sugar-coated tablet contains 10 mg alpha-tocopherol acetate.

The excipients are: microcrystalline cellulose, lactose monohydrate, talc, magnesium stearate, povidone, gelatin, calcium carbonate, titanium dioxide, sucrose, sunset yellow FCF (E 110),

ponceau 4R (E 124), Sodium benzoate, brilliant blue FCF, shellac carnauba wax and beeswax white, starch sodium octenyl succinate, corn starch, sodium aluminum silicate.

Contents of the pack

Carton box with 60 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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