

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Evitol

100 mg coated tablets

TOCOPHEROL

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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#### What is in this leaflet?

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

#### *1. WHAT EVITOL IS AND WHAT IT IS USED FOR*

Vitamin E is an antioxidant that prevents the oxidation of important cell structure. It binds to the active harmful substances such as free radicals, which are formed in the body under the influence of intra-body and outer-body factors. In this way it protects cells from damage and preserves their functional ability.

Vitamin E has a positive effect on the entire body: improves immune resistance, prevents damage to blood vessels and protects them from atherosclerotic changes, and facilitates the absorption of other vitamins.

#### ***Evitol tablets are recommended:***

For the prevention and treatment of vitamin E deficiency,  
In conditions of increased need for vitamin E, such as:

- Increased exposure to stress,
- Great physical exhaustion.

The medicine is not a substitute for a balanced and varied diet.

## 2. BEFORE YOU TAKE EVITOL

### **Do not take EVITOL**

If you are allergic (hypersensitive) to vitamin E, or any of the other ingredients of the medicine Evitol

### **Take special care with EVITOL**

- If you are taking iron, vitamin K or anticoagulants (medicines that prevent blood clotting).
  - If you have a blockage of the bile ducts, the absorption of vitamin E may be reduced because the bile and pancreatic juice are necessary for the absorption.
  - If you suffer from diabetes you can take Evitol but you must be aware that each tablet contains 170 mg of lactose, 539.5 mg of sucrose, 26.1 mg of glucose and 119 mg of sorbitol.
- Evitol is not recommended for children under 14 years.

Consult your doctor or pharmacist before simultaneously taking other vitamins and vitamin and mineral products containing vitamin E.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Vitamin E can reduce the effectiveness of treatment with iron in anemic patients. Iron decreases the effectiveness of vitamin E, if taken simultaneously.

If taken simultaneously, Evitola and estrogen or anticoagulants may increase the risk of bleeding.

Do not take Evitol tablets simultaneously with medicines for the reduction of the amount of fat in the blood because they reduce the absorption of vitamin E. We recommend at least a two-hour time gap.

### **Taking evitol with food and drinks**

EVITOL tablets can be taken together with food.

### **Pregnancy and breast-feeding**

Consult your doctor or pharmacist before taking any medicine.

Pregnant and breastfeeding women may take this medicine only on doctor's advice. Since vitamin E passes into breast milk, we do not recommended self-treatment during breastfeeding.

### **Driving and using machines**

EVITOL should not affect your ability to drive and use machines.

### **Other warnings**

This medicine contains lactose, glucose, sucrose and sorbitol. In case of intolerance to some sugars, contact your doctor before using this medicine.

Azo dyes E110 and E124 may cause allergic reactions.

## 3. HOW TO TAKE EVITOL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults and adolescents over 14 years is 2-3 tablets per day during a meal or after it. The tablet can be dissolved in the mouth or swallow with a glass of water. Evitol tablets can be taken over a longer period of time.

### ***If you take more EVITOL than you should***

If you have taken a higher dose than you should immediately consult your doctor or pharmacist. Although vitamin E is not toxic, high doses of vitamin E (1200 mg daily), taken simultaneously with anticoagulants, prolong blood clotting time.

### ***If you forget to take EVITOL***

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

Talk to your doctor or pharmacist if you have any additional questions.

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, EVITOL can cause side effects, although not everybody gets them. Active medical charcoal colors the stool in black.

In very rare cases, especially at higher doses than recommended, Evitol can cause gastrointestinal problems such as nausea and bloating.

Very rarely it may cause signs of hypersensitivity (rash, pruritus). If they occur, stop taking tablets and consult your doctor or pharmacist.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## ***5. HOW TO STORE EVITOL***

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Shelf life: 2 years.

Do not store above 25 °C. Store in the original package to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## ***6. FURTHER INFORMATION***

### ***What EVITOL contains***

- The active substance is DL- $\alpha$ -tocopheryl acetate. One coated tablet contains 100 mg (i.e. 100) of DL- $\alpha$ -tocopheryl acetate, which corresponds to 67 mg of vitamin E.
- Other ingredients are gelatin, lactose, liquid glucose, sorbitol, glycerol, anhydrous colloidal silica, walnut flavor, magnesium stearate, polysorbate 80, castor oil and virgin dimethylpolysiloxane in the tablet core, and sucrose, 4R red dye (E124), orange color (E110) and pharmaceutically waxes (beeswax, carnauba wax, shellac) in the coating.

### ***What EVITOL looks like and contents of the pack***

Coated tablets are red, round.

There are boxes with 30 coated tablets in blisters. There are 3 blisters with 10 tablets in the box.

***Regime of dispensing***

The medicine is issued without doctor`s prescription.

***Manufacturer***

KRKA d.d. Novo Mesto

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