

PATIENT INFORMATION LEAFLET

Vitamin E Suspension 100mg in 1 ml DL-alpha-tocopheryl acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Vitamin E Suspension is and what it is used for
- 2. What you need to know before you take Vitamin E Suspension
- 3. How to take Vitamin E Suspension
- 4. Possible side effects
- 5. How to store Vitamin E Suspension
- 6. Contents of the pack and other information

1. What Vitamin E Suspension is and what it is used for

DL-alpha-tocopheryl acetate, the active ingredient of Vitamin E Suspension, is a man-made form of vitamin E. Although the exact role of vitamin E has not yet been worked out, it is known to play an important part in metabolism – the chemical reactions that are taking place in the body all the time.

Vitamin E Suspension is used in certain illnesses which prevent the body from absorbing enough vitamin E from the diet. By taking extra vitamin E in the form of Vitamin E Suspension, the body gets all it needs. The medical names for these illnesses are cystic fibrosis (an inherited disorder affecting the lungs, pancreas and other glands), chronic cholestasis (a disease of the liver) and abetalipoproteinaemia (a rare inherited disease which causes a deficiency of fat in the blood and severely affects growth).

2. What you need to know before you take Vitamin E Suspension

Do not take Vitamin E Suspension:

- if you are allergic to Vitamin E or any other ingredients of Vitamin E Suspension (listed in section 6).
- if you have an inherited condition which can cause an intolerance to some sugars

Warnings and precautions

Talk to your doctor or pharmacist before taking Vitamin E Suspension:

- if you have a bleeding condition caused by a lack of Vitamin K.
- if you have ever had a thrombosis (a clot inside a blood vessel).

Speak to your doctor or pharmacist before you take this product if either of these points affects you.

If Vitamin E Suspension has been prescribed for your child, then these warnings also apply to him or her.

If you need any other medical treatment or surgery whilst taking Vitamin E Suspension, remember to tell the doctor or dentist treating you that you are taking this medicine.

Children

Where treatment with Vitamin E is required in severely anaemic infants and low birth-weight infants being treated with iron supplements, blood iron levels will be closely monitored.

Other medicines and Vitamin E Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- colestyramine (a medicine used to treat high cholesterol)
- the oral contraceptive pill
- anticoagulants (medicines to thin your blood).

Excessive doses of Vitamin E may interfere with iron supplement treatment in infants.

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. The effects of high doses of vitamin E during pregnancy and breast feeding are not known. Consequently, Vitamin E Suspension is not recommended during pregnancy and breast feeding.

Driving and using machines

Vitamin E Suspension should not affect your ability to drive or use machinery.

Vitamin E Suspension contains sucrose, benzoic acid, propylene glycol and polyoxyl castor oil

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine contains 1g of sucrose in every 5ml and may be harmful to the teeth.

Polyoxyl castor oil may cause stomach upsets and diarrhoea.

This medicine contains 10 mg benzoic acid in each 5ml. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains 13.99 mg propylene glycol in each 5ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take Vitamin E Suspension

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

The usual doses vary depending upon the age of the patient, the condition for which Vitamin E Suspension was prescribed, and sometimes also the patient's weight. Vitamin E blood levels will be checked by your doctor at regular intervals during treatment and the dose adjusted as necessary.

- For cystic fibrosis:- the usual doses are 0.5ml per day for an infant under one year of age, 1ml per day for older children and 1-2ml per day for adults.
- For chronic cholestasis:- infants with chronic cholestasis may be given 1.5-2ml for each kilogram of body weight per day.
- For abetalipoproteinaemia:- the dose for all ages depends upon bodyweight and is 0.5-1ml per kilogram, daily.

Vitamin E Suspension should be taken by mouth. You may have been given an oral syringe by your pharmacist to help you measure the dose accurately.

Greater amounts will be needed if the Vitamin E Suspension has been diluted before it was given to you. If in any doubt about the correct dosage, follow the instructions on the bottle carefully or ask your pharmacist to explain it to you.

Discard any unused Vitamin E Suspension one month after opening the bottle. Take any unused medicine back to your pharmacist for safe disposal.

If you take more Vitamin E Suspension than you should

If you or anyone else accidentally swallows a large amount of Vitamin E Suspension, do not panic as it is unlikely to cause any serious harm but you may experience a stomach upset. Obtain medical advice from your doctor or pharmacist immediately.

If you forget to take Vitamin E Suspension

Vitamin E Suspension should be taken every day but it is not important to take it at any particular time. There is no need to take extra the following day if you forget to take a dose.

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

4. Possible side effects

Like all medicines Vitamin E Suspension can cause side-effects, although not everybody gets them. It is possible that you might develop diarrhoea or a stomach upset.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the internet at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Vitamin E Suspension

Keep this medicine out of the sight and reach of children – preferably in a locked cupboard or medicine cabinet.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Do not use Vitamin E Suspension for more than one month after you have opened it.

The product may be diluted with syrup BP, but should be used immediately and not stored.

Do not store above 25°C.

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 Vitamin E Suspension contains

The active substance is DL-alpha-tocopheryl acetate, and there is 100mg of this in each ml of your medicine.

The other ingredients are benzoic acid E210, sorbic acid, glycerol, sucrose, raspberry flavour (containing propylene glycol E1520 and natural flavourings), polyoxyl castor oil and purified water.

What Vitamin E Suspension looks like and contents of the pack Each bottle contains 100ml of Vitamin E Suspension.

Marketing Authorisation Holder

Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Manufacturer

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