Package leaflet: Information for the user

Vedrop 50 mg/ml oral solution
(tocofersolan)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of 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. See section 4.

What is in this leaflet

1. What Vedrop is and what it is used for

Vedrop contains vitamin E (in the form of tocofersolan). It is used to treat lack of vitamin E due to digestive malabsorption (where nutrients from the food are not easily absorbed during digestion) in patients from birth (full term newborns) up to 18 years of age suffering from chronic cholestasis (a hereditary or congenital disease where bile cannot flow from the liver to the intestine).

2. What you need to know before you take Vedrop

Do not take Vedrop
- If you are allergic to vitamin E (d-alpha-tocopherol) or any of the other ingredients of this medicine (listed in section 6).
- Vedrop must not be used in newborn premature babies.

Warnings and precautions
Talk to your doctor before taking Vedrop if you have:
- Problems with your kidney or dehydration. Vedrop should be used with caution and your kidney function closely monitored, because polyethylene glycol, part of the active substance tocofersolan, may damage your kidneys.
- Problems with your liver. Vedrop should be used with caution and liver functions closely monitored.

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

Tell your doctor or pharmacist if you are taking:
- Certain medicines to thin the blood (oral anticoagulants such as warfarin). Your doctor will ask you to perform blood tests regularly and may adjust their dose to avoid higher risk of bleeding.
- Fat-soluble vitamins (such as vitamin A, D, E or K) or highly fat-soluble medicines (such as corticoids, ciclosporin, tacrolimus, antihistamine). As Vedrop may increase their absorption during digestion, your doctor will monitor the treatment effect and adjust the doses if necessary.

Pregnancy and breast-feeding
No clinical data are available on exposure to this medicine during pregnancy. Inform your doctor if you are pregnant as he/she will decide if the medicine may be used.
There is no data on whether or not this medicine is present in the breast milk. Inform your doctor if you want to breast-feed. Your doctor will help you decide what is best for you and your child.

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

Driving and using machines
Vedrop is not likely to affect your ability to drive and use machines.

Vedrop contains sodium methyl parahydroxybenzoate (E219) and sodium ethyl parahydroxybenzoate (E215), which may cause allergic reactions (possibly delayed).

Vedrop contains 0.18 mmoles (4.1 mg) sodium per ml. Speak to your doctor if you are on a controlled sodium diet.

3. How to take Vedrop

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

The usual dose is 0.34 ml/kg/day.
Your doctor will prescribe the dose in ml.
The dose will be adjusted by your doctor according to your vitamin E blood level.

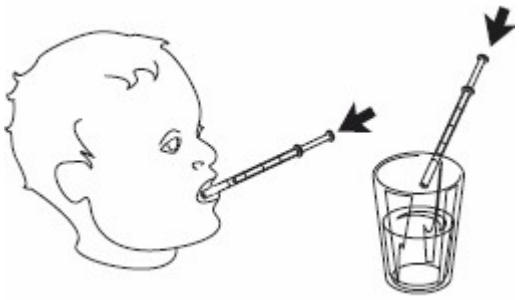
Method of administration
Swallow the solution with or without water. Use only with the oral syringe provided in the box.
You can take Vedrop before or during your meal, with or without water.

To measure the dose:

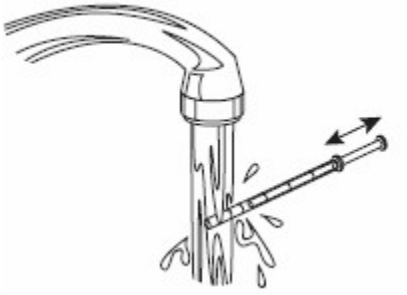
1- Open the bottle.
2- Put the oral syringe included in the pack in the bottle.

3-Fill the oral syringe with the liquid by pulling the plunger up to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor.

4- Remove the oral syringe from the bottle.
5- Empty the contents of the syringe by pushing the plunger to the bottom either:
- directly into the mouth,
or
- into a glass of water and then drink the entire content of the glass.



6- Close the bottle.
7- Wash the syringe with water.



If you take more Vedrop than you should
If you take large doses of Vitamin E, you may experience temporary diarrhoea and stomach ache. Talk to your doctor or pharmacist if symptoms persist more than two days.

If you forget to take Vedrop
Skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Vedrop
Do not stop the treatment without consulting your doctor because lack of vitamin E may come back and affect your health. Contact your doctor or pharmacist before stopping.

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

4. Possible side effects

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

The following side effects were reported:

Common side effects (may affect up to 1 in 10 people)
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people)

- Asthenia (feeling of weakness)
- Headache
- Loss of hair
- Itching
- Rash (eruption on the skin)
- Abnormal level of sodium in the blood
- Abnormal level of potassium in the blood
- Increase of transaminases (liver enzymes)

Not known (frequency cannot be estimated from the available data)

- Stomach ache

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

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Vedrop

- 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 box and the bottle, after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Discard the bottle one month after first opening, even if some solution remains.

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 Vedrop contains

- The active substance is tocofersolan. Each ml of solution contains 50 mg of d-alpha-tocopherol in the form of tocofersolan, corresponding to 74.5 IU of tocopherol.
- The other ingredients are: potassium sorbate, sodium methyl parahydroxybenzoate (E219) and sodium ethyl parahydroxybenzoate (E215) (see end of section 2 for further information on these 2 ingredients), glycerol, disodium phosphate dodecahydrate, concentrated hydrochloric acid, purified water.

What Vedrop looks like and contents of the pack
Vedrop is a slightly viscous pale yellow oral solution in a brown glass bottle which is closed with a child-resistant cap. The bottles contain 10 ml, 20 ml or 60 ml of oral solution. Each box contains one bottle and one oral syringe (a 1 ml syringe with a 10 ml or 20 ml bottle, a 2 ml syringe with a 60 ml bottle).

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in April 2019

This medicine has been authorised under "exceptional circumstances". This means that because of the rarity of this disease it has been impossible to get complete information on this medicine.
The European Medicines Agency will review any new information on this medicine every year and this leaflet will be updated as necessary.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.