ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Vedrop 50 mg/ml oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 50 mg of d-alpha-tocopherol, in the form of tocofersolan, corresponding to 74.5 IU of tocopherol.

Excipients:
Each ml contains 6 mg sodium methyl parahydroxybenzoate (E219), 4 mg sodium ethyl parahydroxybenzoate (E215) and 0.18 mmoles (4.1 mg) of sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

Slightly viscous, pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vedrop is indicated in vitamin E deficiency due to digestive malabsorption in paediatric patients with congenital chronic cholestasis or hereditary chronic cholestasis, from birth (full term newborns) up to 18 years of age.

4.2 Posology and method of administration

The treatment with Vedrop should be initiated and supervised by a physician experienced in the management of patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis.

Bioavailability of vitamin E from Vedrop differs from that of other medicinal products. The dose should be prescribed in mg of d-alpha-tocopherol in the form of tocofersolan. Plasma vitamin E level should be monitored monthly for at least the first few months of therapy, thereafter at regular intervals and the dose adjusted accordingly if necessary.

Posology
The recommended total daily dose in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis is 0.34 ml/kg/day (17 mg/kg of d-alpha-tocopherol in the form of tocofersolan). The dose should be prescribed in ml.

The dose should be adjusted according to plasma vitamin E level.

To calculate the dose of Vedrop to be administered, divide the prescribed dose of d-alpha-tocopherol (in mg) by 50. The result is the volume of Vedrop in ml:

$$\text{Dose of Vedrop (in ml)} = \frac{\text{dose of d-alpha-tocopherol (in mg)}}{50}$$

The following table gives the volume of oral solution in function of patients' weights.

Weight (kg)	**Oral solution volume (ml)**
3	1.0
4	1.4
5	1.7
6	2.0
7	2.4
8	2.7
9	3.1
10	3.4
15	5.1

Special populations
Hepatic or renal impairment
Experience with tocofersolan therapy in patients with renal impairment or underlying liver impairment has demonstrated no need to adapt the dose regimen of Vedrop (see section 4.4).

Method of administration
Vedrop is administered orally with or without water. The 1-ml or 2-ml oral syringes included in the container are designed to assist in measuring out the exact dose in accordance with the prescribed posology.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Vedrop must not be used in preterm newborn infants.

4.4 Special warnings and precautions for use

As large doses of vitamin E have been reported to increase bleeding tendency in vitamin-K deficient patients or those taking oral anti-vitamins K treatment, it is therefore recommended to monitor the prothrombin time and international normalised ratio (INR). A possible adjustment of the dose of oral anticoagulant during and after treatment with Vedrop may be necessary.

As data on patients with renal impairment are limited, Vedrop should be administered with caution and under close monitoring of the renal function in patients with renal impairment e.g. dehydrated patients (see section 4.2).

Vedrop should be administered with caution in patients with underlying liver impairment and under close monitoring of the hepatic functions in such patients (see section 4.2).

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

This medicinal product contains sodium. It should be taken into consideration by patients on a controlled sodium diet.

4.5 Interactions with other medicinal products and other forms of interaction

No interaction studies have been performed.

It is recommended to monitor the coagulation function when administered with anti-vitamins K treatment (see section 4.4).

Due to inhibition of P-Glycoprotein transporter, tocofersolan may also enhance intestinal absorption of other concomitant fat-soluble vitamins (A, D, E, K) or that of highly lipophilic medicinal products (such as steroids, antibiotics, antihistamines, cyclosporine, tacrolimus). Therefore, monitoring should be performed and, when necessary, doses should be adjusted.

4.6 Fertility, pregnancy and lactation

Pregnancy
For tocofersolan no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development (see section 5.3). Caution should be exercised when prescribing to pregnant women.

Breast-feeding
It is unknown whether tocofersolan is excreted in human breast milk. The excretion of tocofersolan in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Vedrop should be made taking into account the benefit of breast-feeding to the child and the benefit of tocofersolan therapy to the woman.

Fertility
No data is available

4.7 Effects on ability to drive and use machines

Vedrop has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
The most commonly reported adverse reaction during treatment is diarrhoea.

Tabulated list of adverse reactions
Reported adverse reactions are listed below, by system organ class and by frequency.
Frequencies are defined as*:* very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).
Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System organ class	Adverse reactions
Gastrointestinal disorders	*Common*: diarrhoea *Not known*: abdominal pain
Skin and subcutaneous tissue disorders	*Uncommon*: alopecia, pruritus, rash
General disorders and administration site conditions	*Uncommon*: asthenia, headache
Investigations	*Uncommon:* serum sodium abnormal, serum potassium abnormal, transaminases increase

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Large vitamin E doses may cause diarrhoea, abdominal pain, and other gastrointestinal disturbances.
In case of overdose, a symptomatic treatment should be proposed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vitamins, Other plain vitamin preparations; ATC code: A11HA08

Vitamin E is the principal lipo-soluble antioxidant in the organism. It acts as a free radical chain breaking molecule, stopping the peroxidation of polyunsaturated fatty acids and it is involved in maintaining the stability and integrity of cell membranes.

This medicinal product has been authorised under "exceptional circumstances". This means that due to the rarity of the disease it has not been possible to obtain complete information on this medicinal product.
The European Medicines Agency will review any new information which may become available every year and this SmPC will be updated as necessary.

5.2 Pharmacokinetic properties

Absorption
The active substance d-alpha-tocopherol-polyethylene glycol 1000 succinate (tocofersolan) is a pro-drug; the active metabolite is the d-alpha-tocopherol. At low concentrations, tocofersolan forms micelles which enhance absorption of non-polar lipids such as fat-soluble vitamins. Its critical micellar concentration is low (0.04 to 0.06 mmol/l).

The hydrolysis of tocofersolan occurs in the gut lumen. Taken up by cells, the alpha-tocopherol moiety appears in chylomicrons in the lymph in a manner identical to vitamin E absorbed from the diet. Cellular uptake does not require receptors, binding proteins or metabolic processes and does not occur by pinocytosis. Absorption of deuterated tocofersolan showed a normal pattern in lipoproteins: alpha-tocopherol peaked first in chylomicrons, then in very low- density lipoproteins (VLDL) and finally in low-density lipoproteins (LDL) and high-density lipoproteins (HDL), and the disappearance portions of the curves paralleled those in control subjects.

A study in 12 healthy volunteers compared tocofersolan with a water-miscible reference vitamin E after a single oral loading dose of 1200 IU. The relative bioavailability of tocofersolan tended to be higher (F_{rel} of 1.01 ± 1.74) with AUC_{0-t} of 0.383 ± 0.203µM.h/mg, C_{max} of 0.013 ± 0.006, t_{max} of 6.0 h (6.0 – 24.0), and $t_{1/2}$ of 29.7 h (16.0 – 59.5).

In a similar study tocofersolan showed a higher bioavailability than a water-miscible reference vitamin E in paediatric patients with chronic cholestasis (n=6), absorption was significantly higher on both plasma concentration maximum increase (p=0.008) and AUC (p=0.0026).

Distribution
Located principally on cell membranes, within mitochondria and microsomes, vitamin E is ubiquitously distributed (red blood cells, brain, muscle, liver, platelets) and fat tissues are its major reservoir.

Elimination
Vitamin E is mainly eliminated in the bile (75%) and stools, either as free tocopherol or as oxidized forms. Urine represents a minor elimination route of vitamin E (as glucuro-conjugate).

5.3 Preclinical safety data

Non-clinical data in the literature reveal no special hazard for humans based on conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate
Sodium methyl parahydroxybenzoate (E219)
Sodium ethyl parahydroxybenzoate (E215)
Glycerol
Disodium phosphate dodecahydrate
Concentrated hydrochloric acid
Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years.

After first opening the bottle: 1 month.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Type III brown glass bottle with a child-resistant screw cap of HDPE and LDPE seal. Oral syringes with housing of LDPE and piston of polystyrol. Each bottle contains 10 ml, 20 ml or 60 ml of oral solution.

Boxes containing:

- one 10 ml bottle and one 1 ml oral syringe
- one 20 ml bottle and one 1 ml oral syringe
- one 60 ml and one 2 ml oral syringe

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Doses for administration should be extracted from the bottle using the oral syringes which are provided in the pack.

The 1 ml oral syringe is graduated from 0.05 to 1 ml in steps of 0.05 ml. One graduation of the 1 ml oral syringe corresponds to 2.5 mg of d-alpha-tocopherol in the form of tocofersolan.

The 2 ml oral syringe is graduated from 0.1 to 2 ml in steps of 0.1 ml. One graduation of the 2-ml oral syringe corresponds to 5 mg of d-alpha-tocopherol in the form of tocofersolan.

7. MARKETING AUTHORISATION HOLDER

Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
92800 Puteaux
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/533/001 10ml bottle
EU/1/09/533/002 20ml bottle
EU/1/09/533/003 60ml bottle

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 July 2009
Date of latest renewal: 23 April 2014

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
92800 Puteaux
France

or

Recordati Rare Diseases
Eco River Parc
30, rue des Peupliers
F-92000 Nanterre
France

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk Management Plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time.

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

This being an approval under exceptional circumstances and pursuant to Article 14(8) of Regulation (EC) No 726/2004, the MAH shall conduct, within the stated timeframe, the following measures:

Description	Due date
The MAH shall provide yearly updates on any new information concerning efficacy and safety of the product in patients with congenital chronic cholestasis or hereditary cholestasis.	Yearly, simultaneously with submission of Periodic Safety Update reports

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box – 10 ml, 20 ml and 60 ml bottle

1. NAME OF THE MEDICINAL PRODUCT

Vedrop 50 mg/ml oral solution
Tocofersolan

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains 50 mg of d-alpha-tocopherol in the form of tocofersolan, corresponding to 74.5 IU of tocopherol.

3. LIST OF EXCIPIENTS

Excipients: sodium methyl parahydroxybenzoate (E219), sodium ethyl parahydroxybenzoate (E215). See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral solution.

Bottle of 10 ml and 1 ml oral syringe.
Bottle of 20 ml and 1 ml oral syringe.
Bottle of 60 ml and 2 ml oral syringe.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Discard one month after first opening.

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
92800 Puteaux
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/533/001 10 ml bottle
EU/1/09/533/00 2 20 ml bottle
EU/1/09/533/003 60 ml bottle

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Vedrop 50 mg/ml

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle label – 10 ml, 20 ml and 60 ml bottles

1. NAME OF THE MEDICINAL PRODUCT

Vedrop 50 mg/ml oral solution.
Tocofersolan

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains 50 mg of d-alpha-tocopherol in the form of tocofersolan, corresponding to 74.5 IU of tocopherol.

3. LIST OF EXCIPIENTS

Excipients: sodium methyl parahydroxybenzoate (E219), sodium ethyl parahydroxybenzoate (E215). See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral solution.

10 ml 20 ml 60 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Discard one month after opening

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
92800 Puteaux
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/533/001 10 ml bottle
EU/1/09/533/002 20 ml bottle
EU/1/09/533/003 60 ml bottle

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Vedrop 50 mg/ml

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

B. PACKAGE LEAFLET

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
2. What you need to know before you take Vedrop
3. How to take Vedrop
4. Possible side effects
5. How to store Vedrop
6. Contents of the pack and other information

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.

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..

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.

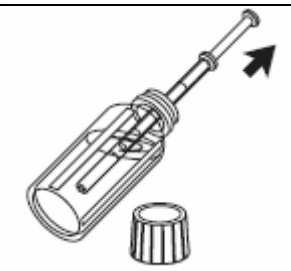
The usual dose is 0.34 ml/kg/day.
Your doctor will prescribe the dose in ml.
The dose will be adjusted by your doctor according to your vitamin E blood level.

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.

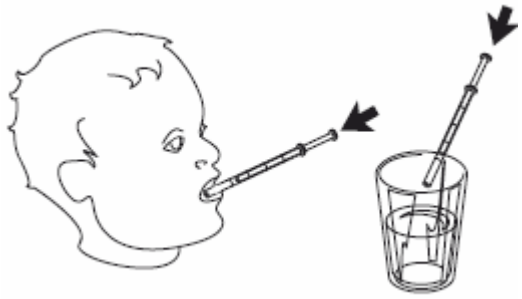
To measure the dose:

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

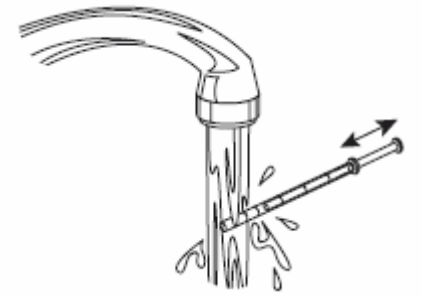
3-Fill the oral syringe with the liquid by pulling the plunger up to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor.



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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. 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).

Marketing Authorisation Holder

Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
92800 Puteaux
France

Manufacturer
Recordati Rare Diseases
Tour Hekla
52 avenue du Général de Gaulle
F-92800 Puteaux
France

or

Recordati Rare Diseases
Eco River Parc
30, rue des Peupliers
F-92000 Nanterre
France

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

Belgique/België/Belgien
Recordati
Tél/Tel: +32 2 46101 36

България
Recordati Rare Diseases
Тел.: +33 (0)1 47 73 64 58
Франция

Česká republika
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Francie

Danmark
Recordati AB.
Tlf : +46 8 545 80 230
Sverige

Deutschland
Recordati Rare DiseasesGermany GmbH
Tel: +49 731 140 554 0

Eesti
Recordati AB.
Tel: + 46 8 545 80 230
Rootsi

Ελλάδα
Recordati Rare Diseases
Τηλ: +33 1 47 73 64 58
Γαλλία

Lietuva
Recordati AB.
Tel: + 46 8 545 80 230
Švedija

Luxembourg/Luxemburg
Recordati
Tél/Tel: +32 2 46101 36
Belgique/Belgien

Magyarország
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Franciaország

Malta
Recordati Rare Diseases
Tel: +33 1 47 73 64 58
Franza

Nederland
Recordati
Tel: +32 2 46101 36
België

Norge
Recordati AB.
Tlf : +46 8 545 80 230
Sverige

Österreich
Recordati Rare DiseasesGermany GmbH
Tel: +49 731 140 554 0
Deutschland

España
Recordati Rare Diseases SpainS.L.U.
Tel: + 34 91 659 28 90

France
Recordati Rare Diseases
Tél: +33 (0)1 47 73 64 58

Hrvatska
Recordati Rare Diseases
Tél: +33 (0)1 47 73 64 58
Francuska

Ireland
Recordati Rare Diseases.
Tel: +33 (0)1 47 73 64 58
France

Ísland
Recordati AB.
Simi:+46 8 545 80 230
Svíþjóð

Italia
Italy Srl
Tel: +39 02 487 87 173

Κύπρος
Recordati Rare Diseases
Τηλ : +33 1 47 73 64 58
Γαλλία

Latvija
Recordati AB.
Tel: + 46 8 545 80 230
Zviedrija

Polska
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Francja

Portugal
Recordati Rare Diseases SARL
Tel: +351 21 432 95 00

România
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Franţa

Slovenija
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Francija

Slovenská republika
Recordati Rare Diseases
Tel: +33 (0)1 47 73 64 58
Francúzsko

Suomi/Finland
Recordati AB.
Puh/Tel : +46 8 545 80 230
Sverige

Sverige
Recordati AB.
Tel : +46 8 545 80 230

This leaflet was last revised in

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.