SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Mixed tocotrienols 50 mg soft gelatin capsules
Trieovid suprabio 50 mg

Mixed tocotrienols 200 mg soft gelatin capsules
Trieovid suprabio 200 mg

2. Qualitative and quantitative composition

Trieovid suprabio 50 mg
Each tablet contains 15.38 mg of d-α-tocotrienol, 28.20 mg of d-γ-tocotrienol, 6.42 mg of d-δ-tocotrienol, 22.90 IU of d-α-tocopherol, 12.82 mg of plant squalene, 5.12 mg of phytosterol complex and 90.00 µg of phytocarotenoid complex.

Trieovid suprabio 200 mg
Each tablet contains 61.52 mg of d-α-tocotrienol, 112.80 mg of d-γ-tocotrienol, 25.68 mg of d-δ-tocotrienol, 91.60 U of d-α-tocopherol, 51.28 mg of plant squalene, 20.48 mg of phytosterol complex and 360 µg of phytocarotenoid complex.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Soft gelatin capsule.

Trieovid suprabio 50 mg
Reddish-brown soft gelatin capsule.

Trieovid suprabio 200 mg
Reddish-brown soft gelatin capsule.

4. Clinical particulars

4.1 Therapeutic indications

Mixed tocotrienols (T3) are potent antioxidants which protect the body cells from damage as a substitute target for free radicals.

Trieovid suprabio possesses a higher content of δ- and γ-tocotrienols. These have been shown in studies to have potential in lowering cholesterol and atherosclerosis.

4.2 Posology and method of administration

Posology
The usual doses vary depending upon the condition for which mixed tocotrienols were prescribed (patient's age and weight). The minimum recommended dose is 50 mg of mixed tocotrienols to a maximum recommended dose of 200 mg mixed tocotrienols daily.

Trieovid suprabio should be taken every day but it is not important to take it at any particular time.

Method of administration
Oral use.

4.3 Contraindications
Hypersensitivity to the tocotrienols or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
Mixed tocotrienols may increase bleeding tendency in vitamin-K deficient patients or those taking anticoagulant treatments, it is therefore recommended to monitor the prothrombin time and international normalised ratio (INR) to detect any changes in haemostasis. A possible adjustment of the dose of anticoagulants during and after treatment may be necessary (see section 4.5).

Mixed tocotrienols may increase the risk of thrombosis in patients predisposed to this condition, including patients taking oestrogens. This finding has not been confirmed but should be borne in mind when selecting patients for treatment, in particular women taking oral contraceptives containing oestrogens.

Serum levels of mixed tocotrienols should be monitored in cholestatic patients undergoing concurrent treatment with colestyramine (see section 4.5). The dose of mixed tocotrienols should be adjusted as necessary.

Mixed tocotrienols in dosages of greater than 4.5 mg/kg daily may delay the response to iron therapy in children with iron-deficiency anaemia. Iron concentrations should be monitored closely.

4.5 Interaction with other medicinal products and other forms of interaction
Mixed tocotrienols may increase the risk of haemorrhage in patients taking anticoagulants (see section 4.4).

Mixed tocotrienols may increase the risk of thrombosis in patients taking oestrogens (see section 4.4).

Colestyramine may reduce the absorption of vitamin E (see section 4.4).

Iron: Limited data suggest that excessive doses of mixed tocotrienols (>4.5 mg/kg/day) can delay the red blood cell response to iron supplements in severely anaemic infants and that low-birth weight infants treated with iron supplements may develop vitamin E-deficiency haemolytic anaemia. High doses of mixed tocotrienols should be avoided in infants. It is not known if this interaction occurs in adults (see section 4.4).

4.6 Pregnancy and lactation
Mixed tocotrienols are not recommended during pregnancy and breastfeeding unless advised by the doctor. The effects of high doses of tocotrienols during pregnancy and breastfeeding are not known.

4.7 Effects on the ability to drive and use machines
Mixed tocotrienols have no influence on the ability to drive and use machines.

4.8 Undesirable effects
None known.

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 Adverse Drug Reaction (ADR)/ Serious Adverse Event (SAE) electronic form linked to the MCAZ database using the following link: https://primaryreporting.who-umc.org/ZW.

4.9 Overdose
The most likely manifestation of overdose is anticipated to be a stomach upset.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacological classification: 24.1.5 Vitamin E and analogues.

Tocotrienols protect the body cells from damage by being a substitute target for free radicals.

Free radicals are very reactive and attack healthy cells. Exposure to free radicals is mostly from air pollution, cigarette smoke, UV radiation, fried or burnt food and food contamination like pesticides. If their effects are not neutralized, free radicals may pose a potential health hazard to the body.

Tocotrienols are mostly extracted in their natural form from palm oil and rice bran oil. Among these two, palm tocotrienols possess a higher content of δ- and γ-tocotrienol, two of the more potent tocotrienols.

5.2 Pharmacokinetic properties
Mixed tocotrienols are absorbed from the gastrointestinal tract. Most of the tocotrienols appear in the lymph and are then widely distributed to all tissues. Most of the dose is slowly excreted in the bile.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients
Palm super olein
Caprylocaproyl macrogoglycerides
Polysorbate 80

Gelatin sheet
Gelatin
Glycerin
Polysorbate 80
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of the container
Trieovid suprabio 50 mg
The tablets are packed in Alu-Alu blister packs.
Pack size: 30 tablets and 60 tablets.

Trieovid suprabio 200 mg
The tablets are packed in a type III amber glass bottle.
Pack size: 30 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT
Hovid Berhad
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar)
Ipoh, Perak
Malaysia

8. MANUFACTURER
Hovid Berhad
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar)
30010 Ipoh, Perak
Malaysia

9. REGISTRATION DETAILS
Trieovid suprabio 50 mg
Zimbabwe registration number: 2023/24.1.5/6518
Zimbabwe category for distribution: Pharmacy Medicines (P)

Trieovid suprabio 200 mg
Zimbabwe registration number: 2023/24.1.5/6519
Zimbabwe category for distribution: Pharmacy Medicines (P)

10. DATE OF REVISION OF TEXT
March 2024