

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product :

1.1 Product Name

Tocovid Suprabio 200mg

1.2 Strength

Each capsule contains Mixed Tocotrienols 200 mg

1.3 Pharmaceutical Dosage Form

Soft gelatin capsule

2-Quality and Quantitative Composition :

2.1 Qualitative Declaration

Name of Ingredient	mg/capsule	Referenced monograph	Function
Active Ingredients			
EVNol 50% Suspension	594.59*	In House	Active
Excipients			
Palm Super Olein RBD	305.41	In house	Diluent
Caprylocaproyl Macrogolglycerides (Labrasol)	50.00	BP	Surfactant
Polyoxyl 35 Castor Oil (Cremophor EL)	50.00	In house	Surfactant
Gelatin Sheet (<i>The gelatin sheet include wastage</i>)			
Gelatin		In-house	Base
Glycerin		In-house	Plasticizer
Polysorbate 80		BP	Antifoaming agent
Purified Water**		USP	Solvent

* 10% overage included

** removed during processing

2.2 Quantitative Declaration

Refer to Section 2.1 (Qualitative Declaration)

3- Pharmaceutical Form :

Reddish oblong brown transparent soft gelatin capsule.

4-Clinical Particulars

4.1 Therapeutic indications

As a health supplement

4.2 Posology and method of administration

For oral use

1 soft gelatin capsules a day

4.3 Contraindications

None known provided dosage instruction is followed.

4.4 Special warning and precautions for use

Safety for use in pregnancy and lactation has not been established.

4.5 Interaction with other medicinal products and other forms of Interactions

None known

4.6 Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machine

NOT APPLICABLE.

4.8 Undesirable effects

None known provided dosage instruction is followed.

4.9 Overdose and special antidotes.

Toxicological and pharmacological studies indicate that palm Tocotrienols are safe even when consumed at doses as high as 2500mg/kg body weight. No adverse effect has been reported. Furthermore, its contents are 100% natural, conferring only the best benefits phytonutrients can offer.

5-Pharmacological Properties :

5.1 Mechanism of Actions and Pharmacology

NOT APPLICABLE.

5.2 Pharmacokinetic Properties

NOT APPLICABLE.

5.3 Preclinical safety Data

NOT AVAILABLE

6-Pharmaceutical Particulars :

6.1 List of excipients

Palm Super Olein RBD
Caprylocaproyl Macroglycerides
Polyoxyl 35 Castor Oil (Cremophor EL)
Gelatin
Glycerin
Polysorbate 80
Purified Water

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture

6.5 Nature and contents of container

Description of packaging material for Tocovid Suprabio 200mg is as below:

Primary Packaging Components

100 ml Amber Glass Bottle (Tocovid) (30's)
Cap for 60/100ml Glass Bottle (Tocovid) (30's)
30 ml Amber Glass Bottle (Tocovid) (10's)
Cap for 30ml Glass Bottle (Tocovid) (10's)
Silica Gel (1g) Plastic

Secondary Packaging Components

Tocovid Suprabio 200mg 30's Unit Box
Tocovid Suprabio 200mg (30's) Label
Tocovid Suprabio Display Box
Tocovid Suprabio 200mg (10's) Label

7-Marketing Authorization Holder :

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

8-Manufacturer Name :

Manufacturing Site (Encapsulation)

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Packing site & Final batch release

Name : HOVID Bhd.
Address : Lot 56442, 7 ½ Miles,
Jalan Ipoh / Chemor,
31200 Chemor,
Perak., Malaysia.

9-Date of first authorization/renewal of the authorization :

Oct 2009 / May 2020

10-Date of revision of the text :

May 2019