Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Venaforce Varicose Veins gastro-resistant tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 157.5 - 225.0 mg of extract (as dry extract) from fresh *Aesculus hippocastanum* L, semen (horse chestnut seed) corresponding to 50 mg triterpene glycosides, calculated as anhydrous β-aescin. Extraction solvent: Ethanol 60 % m/m.

Excipient with known effect:

Each gastro-resistant tablet contains 12.5 mg of soya polysaccharide.

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant tablet (tablet)
It is a biconvex, oval-shaped, yellowish-beige coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product for relieving the symptoms of varicose veins such as tired, aching or heavy legs exclusively based on long standing use.

This product is indicated for use in adults.

4.2 Posology and method of administration

Posology

Adults and older people: one tablet twice daily taken immediately after food.

Tablet should be swallowed whole.
Do not exceed the recommended dose.

This product should not be given to children and adolescents under the age of 18 years.

If symptoms persist, worsen or do not improve after 2 weeks use of Venaforce a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration

For oral short-term use only.

4.3 Contraindications

This product should not be used by patients who have an allergy or are hypersensitive to horse chestnut seed or any of the other ingredients listed in section 6.1.

Contains soya. If you are allergic to peanut or soya, do not use this medicinal product.

4.4 Special warnings and precautions for use

If symptoms persist, worsen or do not improve after 2 weeks use of Venaforce a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted immediately as this may be a sign of serious disease.

Patients who have developed ulcers on their lower limbs due to chronic venous insufficiency should not use this product if they are not receiving medical care for their venous ulcers. If a patient develops a venous ulcer while using this product they should immediately seek medical treatment for the ulceration.

4.5 Interaction with other medicinal products and other forms of interaction

None reported

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Undesirable effects associated with the use of horse chestnut seed extracts are generally mild. The following undesirable effects have been reported in clinical studies:

Uncommon (≥1/1,000 to <1/100)
Gastrointestinal disorders:

- Nausea
- Vomiting
- Abdominal Pain
- Flatulence
- Diarrhoea Rare (≥1/10,000 to <1/1,000) Skin and subcutaneous tissue disorders:

- Pruritis
- Rash
- Urticaria
- Erythema
- Eczema

Headache and dizziness have also been reported. The frequency is not 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

No cases of overdose have been reported. In the event of an overdose, patients may expect an increased likelihood of experiencing an undesirable effect. If symptoms develop, medical advice should be sought.

Management of an overdose should include appropriate symptomatic and supportive treatment as warranted by the clinical situation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No pharmacodynamic studies have been undertaken with horse chestnut seed extracts. The pharmacodynamic properties are unknown.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been conducted with horse chestnut seed extracts.

5.3 Preclinical safety data

An *in vitro* study has shown the extract used in Venaforce to be non-mutagenic.
Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Microcrystalline Cellulose
Maize Starch
Colloidal Anhydrous Silica
Soya polysaccharide
Copovidone

Film coating:
Methacrylic Acid – Ethyl Acrylate Copolymer (1:1) Dispersion 30 per cent
Methacrylic Acid – Methyl Methacrylate Copolymer (1:1)
Talc
Triethyl Citrate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glassbottle (type III glass) with coated aluminium foil seal and aluminium pilfer-proof screw cap fitted with a polyseal expanded polyethylene liner.

Pack sizes: 30 and 60 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
Unit 3D, Killeen Road
Dublin 10
D10 TY20
Ireland

8 REGISTRATION NUMBER(S)

TR2309/011/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 16th December 2011
Date of last renewal: 15th December 2016

10 DATE OF REVISION OF THE TEXT

November 2022