SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Venaforce Horse Chestnut GR* tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gastro-resistant tablet contains 157.5–225.0 mg of extract (as dry extract) from fresh Horse chestnut seeds (Aesculus hippocastanum L., semen) corresponding to 50 mg triterpene glycosides, calculated as anhydrous β-aescin.

Extraction solvent: ethanol (60% m/m)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant, tablet for oral use.

It is a biconvex, oval-shaped, yellowish-beige coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product that has been used for the relief of symptoms associated with chronic venous insufficiency and varicose veins, such as tired heavy legs, pain, cramps and swelling, based on traditional use only.

4.2 Posology and method of administration

Adults: one tablet twice daily taken immediately after food.

Tablet should be swallowed whole.

Do not exceed the recommended dose.

Tablets are for oral use only.

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

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.

4.4. Special warnings and precautions for use

If symptoms worsen or persist for more than two weeks medical advice should be sought.

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.

This product contains soya oil polysaccharide and should not be used by patients who are allergic to peanut or soya.

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.

Studies on fertility have not been performed.

4.7 Effects on ability to drive and use machines

This product has no influence on the ability to drive and use machines.

4.8 Undesirable effects

- Gastrointestinal complaints (nausea, vomiting, diarrhoea, abdominal pain and discomfort)

- Allergic reactions (hypersensitivity reactions of the skin, itching, rash, erythema, eczema)
- Headache and vertigo

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

The non-clinical toxicology data available are limited.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

For the tablet:

Microcrystalline cellulose

Maize starch

Colloidal silica, anhydrous

Soya polysaccharide

Copovidone

For the tablet 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.

Keep out of the reach and sight of children.

6.5 Nature and contents of container

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

Pack sizes: 30 tablets
60 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

A.Vogel Ltd,
2 Brewster Place,
Irvine
KA11 5DD, UK
Tel: 01294 277344
enquiries@avogel.co.uk

8 MARKETING AUTHORISATION NUMBER(S)

THR 13668/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/02/2008

10 DATE OF REVISION OF THE TEXT

17/02/2020