

Professional Information for ANTISTAX[®] ACTIVE LEG TABLETS

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

ANTISTAX[®] ACTIVE LEG TABLETS, 360 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 360 mg of dry extract of red vine leaves (4:6-1) (*Extractum Vitidis viniferae foliae aquosum siccum*; Extraction agent: water).

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets.

Brownish-red, oblong, biconvex, unscored, film-coated tablet with an aromatic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ANTISTAX has been used for the symptomatic relief of symptoms associated with mild to moderately severe varicose veins such as heavy or tired legs, sensation of tension, tingling and pain.

4.2 Posology and method of administration

Posology

The recommended dose for adults is 1 film-coated tablet (360 mg daily). The dose may be increased to 2 film-coated tablets (720 mg) daily to be taken in the morning. The film-coated tablets are to be swallowed whole with water before meals.

Efficacy beyond 12 weeks was not studied.

Paediatric population

No data are available.

4.3 Contraindications

ANTISTAX should not be used in patients known to be hypersensitive to red vine leaf extracts or any other of the components of the product (see section 6.1).

4.4 Special warnings and precautions for use

If a sudden swelling, reddening of the skin, feeling of tension or heat and pain appear, especially in one leg, a doctor should be consulted. These symptoms may be due to thrombophlebitis.

In the event of inadequate or unsatisfactory symptomatic response within six weeks, re-evaluate the patient as the symptoms may have alternative causes.

4.5 Interaction with other medicines and other forms of interaction

Caution is advised when ANTISTAX are used concomitantly with other medicines that are metabolised by CYP450 enzymes. No formal interactions studies have been conducted.

4.6 Fertility, pregnancy and lactation

ANTISTAX are not recommended during pregnancy or in nursing mothers. There are no studies in pregnant women or nursing mothers. There are no studies on the effects of ANTISTAX on fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Frequency classes: Very common ($\geq 1/10$); common ($\geq 1/100$, $< 1/10$); uncommon ($\geq 1/1\ 000$, $< 1/100$); rare ($\geq 1/10\ 000$, $< 1/1\ 000$); very rare ($< 1/10\ 000$); Not known (cannot be estimated from the available data).

Immune system disorders:

Uncommon: Hypersensitivity.

Gastrointestinal disorders:

Uncommon: Nausea, stomach discomfort and other symptoms involving the digestive system.

Skin and subcutaneous tissue disorders:

Uncommon: Generalized pruritic rash and urticaria.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of ANTISTAX is important. It allows continued monitoring of the benefit/risk balance of ANTISTAX. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions**”

Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In case of overdosage, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A 32.2 Other.

Red vine leaf extract is a complex mixture of different classes of compounds of which some flavon / flavonol glucosides and glucuronides were identified. Non-clinical studies *in vitro*, in rats and rabbits showed that red vine leaf extract protects the vascular epithelium by stabilising the membranes and increasing the elasticity (normalisation of the vascular permeability). Reduction in the extravasation of plasma, proteins or water into the interstitial tissue surrounding the venous vessels inhibits the formation of oedemas and reduces existing oedema.

5.2 Pharmacokinetic properties

No pharmacokinetic studies were done because ANTISTAX is a complex mixture.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate (anhydrous), microcrystalline cellulose, croscarmellose sodium, crospovidone, ferric oxide red (E 172), silica colloidal (anhydrous), hypromellose, glyceryl tristearate, magnesium stearate, talc, titanium dioxide (E 171), water purified.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C. Keep protected from humidity, in the original package. Do not remove from the blister until use.

6.5 Nature and contents of container

ANTISTAX are packed in blister strips consisting of colourless, transparent plastic foil and printed aluminium foil. The product name, company name, lot and expiry date are printed on the aluminium foil. The blister strips are packed in printed cardboard cartons containing 30, 60 or 90 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Imperial Market Access Healthcare SA (Pty) Ltd

10 Skeen Boulevard

Bedfordview

Gauteng, 2007

RSA

8. REGISTRATION NUMBER

48/32.2/1076

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15 December 2022

10. DATE OF REVISION OF THE TEXT