

PIL -Format as per PIL guideline 2.14PILMay04v2

(Based on the following : ANTISTAX BPI No. 0200-03 dated 23/05/2006 and the proposed ANTISTAX active leg tablets Package Insert dated 02 March 2007.)

PATIENT INFORMATION LEAFLET _____

Read the entire leaflet carefully because it contains important information for you.

This medicine is available without a doctor's prescription, for you to treat mild symptoms. Nevertheless you still need to use ANTISTAX active leg tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen.

SCHEDULING STATUS: Not scheduled

ANTISTAX[®] active leg tablets

Film coated tablets

Dry extract of red vine leaf AS 195



1. WHAT ANTISTAX TABLETS CONTAIN

- The active substance per tablet is 360 mg of a preparation of dry extract of red vine leaf AS 195 (4 – 6:1), which corresponds to 96 % of dry (pure) extract of red vine leaf and 4 % of colloidal anhydrous silica.

Bio-active flaven

The red vine leaf extract contains bio-active flaven, pharmacologically important flavonoids. Animal studies have shown that red vine leaf extract and its flavonoids strengthen and stabilize the vein walls. Capillary permeability was reduced and this led to a reduction in swelling.

A number of clinical studies have evaluated the effect of bio-active flaven on a variety of symptoms associated with venous disorders.

Clinical data indicate that flavonoids are more effective than placebo in reducing aching, tired and heavy legs. Flavonoids have also been shown to aid in the reduction of oedema (swelling). Thus there is good evidence that flavonoids are helpful in alleviating symptoms in patients with venous disorders.

In a double-blind, placebo controlled study, 260 men and women with chronic venous insufficiency (CVI) were divided into three groups. The first group received a daily dose of ANTISTAX 360 mg capsules*, the second group received 2 x ANTISTAX 360 mg capsules* and the third group received placebo. After 12 weeks of treatment with ANTISTAX there was a marked reduction in leg oedema (swelling). A decrease in ankle and calf measurements as well as a reduction in subjective symptoms related to CVI (tired, heavy legs, sensation of tension in the legs, tingling sensation in the legs and pain in the legs) was seen in patients receiving ANTISTAX. ANTISTAX was well tolerated at both dose levels.

* The ANTISTAX capsules used in this study and ANTISTAX film coated tablets show comparable dissolution profiles. Therefore, the results from this study are applicable to ANTISTAX film coated tablets as well.

The other ingredients are calcium hydrogen phosphate (anhydrous), croscopovidone, croscarmellose sodium, ferric oxide red (E172), glyceryl tristearate, hypromellose, microcrystalline cellulose, magnesium stearate, silica colloidal (anhydrous), talc, titanium dioxide (E171) and water (purified).

None of the ingredients of ANTISTAX tablets are derived from animal origin.

2. WHAT ANTISTAX TABLETS ARE USED FOR

ANTISTAX TABLETS are used to relieve the symptoms associated with chronic venous insufficiency (CVI), in association with varicose veins, including swelling of the lower leg, heavy or tired legs, sensation of tension, tingling and pain.

3. BEFORE YOU TAKE ANTISTAX TABLETS

Do not take ANTISTAX TABLETS:

- If you are hypersensitive (allergic) to any of the ingredients in this product. (Refer to “WHAT ANTISTAX TABLETS CONTAIN”, above.)

Should the condition not improve within six weeks, please consult your medical practitioner.

Pregnancy and Breast-feeding:

Safety in pregnancy and breast-feeding has not been established.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

4. HOW TO TAKE ANTISTAX TABLETS

The dosage of ANTISTAX TABLETS is:

- Adults: Take one film coated tablet (360 mg) in the morning. The dose may be increased to two film coated tablets daily. Swallow the tablets whole with water before breakfast.

If you take more ANTISTAX TABLETS than you should:

No cases of overdose have been reported thus far.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE-EFFECTS

ANTISTAX TABLETS can have side-effects.

ANTISTAX TABLETS may cause:

- Allergic reactions, including an itchy rash and hives
- Digestive system symptoms, such as stomach discomfort and nausea

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist, or other health care professional for advice.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ANTISTAX TABLETS

Keep all medicines out of reach and sight of children.

Store ANTISTAX TABLETS below 25 °C.

Do not take this medicine after the expiry date stated on the carton. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ANTISTAX TABLETS

Cartons containing three PVC/PVDC/aluminium blister strips of ten tablets each.

8. IDENTIFICATION OF ANTISTAX TABLETS

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

9. REGISTRATION NUMBER

Not applicable

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE APPLICANT

Ingelheim Pharmaceuticals (Pty) Ltd
Pine Avenue
Randburg
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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

16 March 2007

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INLIGTINGSBLAD VIR PASIËNTE _____

Lees die voubiljet in sy geheel noukeurig deur, want dit bevat inligting wat belangrik is vir u.

Hierdie medisyne word sonder 'n doktersvoorskrif aan u beskikbaar gestel om self u ligte simptome te behandel. U moet nogtans ANTISTAX tablette versigtig gebruik om die beste resultate daarmee te behaal.

- Hou hierdie pamflet. U sal dit dalk benodig om weer te lees.
- Raadpleeg u apteker indien u nog inligting of raad benodig.
- U moet 'n dokter spreek indien u simptome vererger.

SKEDULERINGSSTATUS: Nie geskeduleerd nie

ANTISTAX[®] active leg tablets

Filmbedekte tablette

Droë ekstrak van rooi wingerdblaar AS 195



1. WAT ANTISTAX TABLETTE BEVAT

- Die aktiewe bestanddeel per tablet is 360 mg van 'n bereiding van droë ekstrak van rooi wingerdblaar AS 195 (4 – 6:1), wat ooreenstem met 96 % van droë (suiwer) ekstrak van rooi wingerdblaar en 4 % watervrye kolloïdale silika.

Bio-actiewe flavien

Die rooi wingerdstok blaarekstrak bevat farmakologies belangrike flavonoïedes bv. bio-actiewe flavien. Studies in diere het aangetoon dat die rooi wingerdstok blaarekstrak en sy flavonoïedes die wande van are verstewig en stabiliseer. Kapillêre deurlaatbaarheid was verminder en dit het gelei tot 'n afname in swelling.

Verskeie kliniese studies het die effek van bio-actiewe flavien op 'n verskeidenheid simptome wat geassosieer word met veneuse afwykings, geëvalueer.

Kliniese data dui daarop dat flavonoïedes meer doeltreffend is as plasebo in die vermindering van simptome van pynlike, moeë en swaar bene. Daar is ook aangetoon dat flavonoïedes help met die vermindering van edeem (swelling). Dus is daar goeie bewyse dat flavonoïedes help met die verligting van simptome bv. pasiënte met veneuse afwykings.

In 'n dubbelblinde, plasebo-gekontroleerde studie, was 260 mans en vrouens met chroniese veneuse ontoereiktheid (CVO) in 3 groepe verdeel. Die eerste groep het 'n daaglikse dosis van ANTISTAX 360 mg kapsules* ontvang, die tweede groep het 2 x ANTISTAX 360 mg kapsules* ontvang en die derde groep het plasebo ontvang. Na 12 weke van behandeling met ANTISTAX was daar 'n beduidende afname in edeem (swelling) van die bene. 'n Vermindering in enkel-en kuitmates sowel as 'n vermindering in subjektiewe simptome geassosieerd met CVO (moeë swaar bene, sensasie van spanning in die bene, tintelende sensasie en pyn in die bene), is aangetoon in pasiënte wat ANTISTAX ontvang het. ANTISTAX is goed verdra by albei doseringsvlakke.

*Die ANTISTAX kapsules wat in hierdie studie gebruik is, asook ANTISTAX filmbedekte tablette, toon vergelykbare dissolusie profiele. Dus is die resultate van hierdie studie ook toepaslik op ANTISTAX filmbedekte tablette.

Die ander bestanddele is gliseriel tristearaat, hipromellose, kalsiumwaterstoffosfaat (watervry), kolloïdale silika (watervry), krosповидооn, magnesiumstearaat, mikrokristallyne sellulose, natriumkroskarmellose, rooi ysteroksied (E172), talk, titaandioksied (E171), suiwer water.

Nie een van die bestanddele in ANTISTAX is van dierlike oorsprong nie.

2. WAARVOOR ANTISTAX TABLETTE GEBRUIK WORD

ANTISTAX TABLETTE word gebruik vir die verligting van simptome te wyte aan chroniese veneuse ontoereikendheid (CVO), geassosieer met spatare, insluitende geswelde onderste ledemate, swaar of moeë bene, gevoel van spanning, prikkeling en pyn.

3. VOORDAT U ANTISTAX TABLETTE GEBRUIK

Moenie ANTISTAX TABLETTE neem nie:

- Indien u hipersensitief (allergies) is vir enige van die bestanddele in hierdie produk. (Kyk hierbo by "WAT ANTISTAX TABLETTE BEVAT".)

Sou die toestand nie binne 6 weke verbeter nie, raadpleeg asseblief 'n mediese praktisyn.

Swangerskap en borsvoeding:

Veiligheid met swangerskap en borsvoeding is nie vasgestel nie. Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne neem, nader asseblief u dokter, apteker of ander professionele gesondheidsorgkundige om advies.

4. HOE OM ANTISTAX TABLETTE TE NEEM

Die dosis ANTISTAX TABLETTE is:

- Volwassenes: Neem een filmbedekte tablet (360 mg) in die oggend. Die dosis kan verhoog word tot twee filmbedekte tablette daagliks. Sluk die tablette heel in met water, voor ontbyt.

Indien u meer ANTISTAX TABLETTE geneem het as wat u moes:

Geen geval van oordosering is tot dusver aangemeld nie.

In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kry hulp by die naaste hospitaal of gifbeheersentrum.

5. MOONTLIKE NEWE-EFFEKTE

ANTISTAX TABLETTE kan newe-effekte hê.

ANTISTAX TABLETTE kan die volgende veroorsaak:

- Allergiese reaksies, insluitende 'n jeukerige uitslag en galbulte
- Spysverteringstelsel simptome, soos maagongemak en naarheid

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, word by hierdie pamflet ingesluit nie. As u algemene gesondheid versleg terwyl u hierdie medisyne neem, kontak asseblief u dokter, apteker of ander professionele gesondheidsorgkundige om advies.

Indien u enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief u dokter of apteker in.

6. BERGING EN WEGDOENING VAN ANTISTAX TABLETTE

Hou alle medisyne buite bereik en sig van kinders.

Bewaar ANTISTAX TABLETTE benede 25 °C.

Moenie hierdie medisyne ná die vervaldatum wat op die kartonhouer aangedui word, gebruik nie. Besorg ongebruikte medisyne of medisyne wat reeds verval het terug aan u apteker vir veilige wegdoening. Moenie van ongebruikte medisyne ontslae raak deur dit in afvoer- of rioolstelsels (bv. toilette) te gooi nie.

7. AANBIEDING VAN ANTISTAX TABLETTE

Kartonhouers met drie PVC/PVDC/aluminium stolpstrokies met tien tablette elk.

8. IDENTIFIKASIE VAN ANTISTAX TABLETTE

Bruinrooi, langwerpige, bikonvekse, ongegekepte, filmbedekte tablet met 'n aromatiese geur.

9. REGISTRASIENOMMER

Nie van toepassing nie.

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE APPLIKANT

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11. DATUM VAN PUBLIKASIE VAN HIERDIE INLIGTINGSBLAD VIR PASIËNTE

16 Maart 2007.