

Patient information leaflet for ANTISTAX® ACTIVE LEG TABLETS

SCHEDULING STATUS

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

Red vine leaf extract

Sugar free

Read all of this leaflet carefully because it contains important information for you.

ANTISTAX is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ANTISTAX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ANTISTAX with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 6 weeks.

What is in this leaflet:

1. What ANTISTAX is and what it is used for
2. What you need to know before you take ANTISTAX
3. How to take ANTISTAX
4. Possible side effects
5. How to store ANTISTAX
6. Contents of the pack and other information

1. What ANTISTAX ACTIVE LEG TABLETS is and what it is used for

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.

2. What you need to know before you take ANTISTAX ACTIVE LEG TABLETS

Do not take ANTISTAX ACTIVE LEG TABLETS:

- if you are hypersensitive (allergic) to red vine leaf extracts or any of the other ingredients (listed in section 6).

Warnings and precautions:

Take special care with ANTISTAX:

- If a sudden swelling, reddening of the skin, feeling of tension, heat and pain develop in a leg, especially if it is only in one leg, consult a doctor immediately. These symptoms may be due to thrombophlebitis (swelling and redness along a vein which is extremely tender when touched).
- If there is no improvement, or not enough improvement, within 6 weeks, you should consult your doctor as your symptoms may be caused by something else.

Children and adolescents:

No data are available for use in children and adolescents.

Other medicines and ANTISTAX ACTIVE LEG TABLETS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding:

The use of ANTISTAX is not recommended if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines:

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

3. How to take ANTISTAX ACTIVE LEG TABLETS

Always take ANTISTAX exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Take one tablet in the morning. The dose may be increased to two tablets daily. Swallow the tablets whole with water before breakfast.

If you take more ANTISTAX ACTIVE LEG TABLETS than you should:

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

If you forget to take ANTISTAX ACTIVE LEG TABLETS:

If you miss a dose, take it as soon as you remember. If it is nearly time for your next dose, skip the missed dose and go back to your usual dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ANTISTAX may have side effects.

Not all side effects reported for ANTISTAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ANTISTAX, please consult your health care provider for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If any of the following happens, stop taking ANTISTAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Itchy rash or hives.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ANTISTAX. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Nausea (feeling sick).
- Stomach discomfort.
- Other symptoms involving the digestive system.
- Itchy rash or hives.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> .

By reporting side effects, you can help provide more information on the safety of ANTISTAX ACTIVE LEG TABLETS.

5. How to store ANTISTAX ACTIVE LEG TABLETS

Store all medicines out of reach of children.

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

Do not use after the expiry date stated on the carton and blister. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ANTISTAX ACTIVE LEG TABLETS tablets contain:

- The active substance is dry extract of red vine leaves (4:6-1) (*Extractum Vitidis viniferae foliae aquosum siccum*; extraction agent: water). Each tablet contains 360 mg of red vine leaf extract.
- The other ingredients are 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.

What ANTISTAX ACTIVE LEG TABLETS look like and contents of the pack:

Brownish-red, oblong, biconvex (curving outwards on both sides), unscored, film-coated tablet with an aromatic odour.

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.

Holder of certificate of registration:

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