

Package leaflet: Information for the user

Capilarema 75 mg capsules

Aminaftone

Please read this leaflet carefully before you start using this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you are not sure, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same symptoms as the disease.
- If you experience any undesirable effects, including possible undesirable effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What's in this leaflet:

- 1 - What is Capilarema and what is it used for
- 2 - What you need to know before taking Capilarema
- 3 - How to take Capilarema
- 4 - Possible undesirable effects
- 5 - How to preserve Capilarema
- 6 - Package contents and other information

1. What is Capilarema and what is it used for

Capilarema is a venotropic medicine that is used in all situations where capillary structures and functions are altered:

- Chronic venous insufficiency,
- Pre-varicose syndrome,
- Hemorrhoids,
- Gynecological hemorrhages,
- Hemorrhagic diathesis of capillary cause,
- Diabetic and hypertensive retinopathy.

2. What you need to know before you take Capilarema

Do not take Capilarema

- if you are allergic to aminaftone or any of the other ingredients of this medicine (listed in section 6).

Aminaftone may cause haemolytic crises in individuals with a glucose-6-phosphate-dehydrogenase genetic defect in erythrocytes (favism).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Capilarema.

As a result of the product being eliminated mainly through urine, it may have a slight reddish color.

Other medicines and Capilarema

Tell your doctor or pharmacist if you are taking, have recently taken or if you are taking other medicines.

Capilarema with food, beverages and alcohol
Not applicable

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Capilarema should not be given to pregnant women.

Driving and using machines

No effects on the ability to drive and use machines were observed.

3. How to take to use Capilarema

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults:

1 capsule twice a day, also for prolonged periods. In more severe cases, the daily dose may be up to 1 capsule, three times a day.

Use in children: Insufficient clinical data are available on the use of Capilarema in children in the approved therapeutic indication.

It should be taken after meals.

If you take more Capilarema than you should

There are no known cases of overdose in the use of aminaftone and therefore no experience has been recorded. In case of overdose, the patient should be monitored accordingly.

If you forget to take Capilarema

Do not take a double dose to make up for a forgotten dose.

Stop taking Capilarema

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Adverse reactions to the drug have been reported very rarely. Among these very rare cases of hemolytic crisis due to glucose-6-phosphate dehydrogenase deficiency (favismus), in these cases the use of the drug is contraindicated.

Reported adverse reactions originating from clinical trials are listed below by organic systemic classification and frequency.

Frequency is defined as: 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 ($< 1/10,000$).

Blood and lymphatic system disorders	Very rare: haemolytic anaemia (in subjects with G6PD deficiency)
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Immune system disorders	Very rare: hypersensitivity.
Nervous system disorders	Uncommon: headache, dizziness.
Gastrointestinal disorders	Frequent: dyspepsia. Uncommon: upper abdominal pain, nausea.
Skin and subcutaneous tissue disorders	Very rare: rash, pruritus.

Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist or nurse. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>

(preferentially)

or through the following contacts:

Directorate of Drug Risk Management

Parque da Saúde de Lisboa, Av. Brazil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Drug Line: 800222444 (free of charge)

E-mail: farmacovigilancia@infarmed.pt

5. How to store Capilarema

Keep this medicine out of the sight and reach of children.

Store away from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton after the abbreviation used for expiry date.

The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Capilarema contains

The active substance is: Aminaftone

The other excipients are: Microcrystalline cellulose, magnesium stearate, talc, indigotine (E132), erythrosine (E127), titanium dioxide (E171), gelatin and water.

What Capilarema looks like and contents of the pack

Capilarema comes in capsules of size nº 3 in red colour.

It is available in packs of 20 and 60 capsules in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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