

PATIENT INFORMATION LEAFLET

X-VEN 500 mg capsules

For oral use only.

- **Active substance:** Each capsule contains 500 mg calcium dobesilate monohydrate.
- **Excipients:** Maize starch, magnesium stearate, colloidal silicon dioxide, gelatin (bovine gelatin), and titanium dioxide (E171).

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

1. *What X-VEN is and what it is used for?*
2. *Before you use X-VEN*
3. *How to use X-VEN?*
4. *Possible side effects*
5. *How to store X-VEN?*

1. What X-VEN is and what it is used for?

- X-VEN is provided in blister packages containing 30 and 60 capsules. Each capsule contains calcium dobesilate monohydrate as the active substance.
- It is indicated for microvascular circulation dysfunction (especially diabetic dysfunction of ocular vasculature), vascular dysfunction presenting with pain, cramps and inactivity of legs and additionally hemorrhoidal disorders.

2. Before you take X-VEN

If you have diabetes related eye disorder, you should strictly follow the diet recommended by your doctor in order to control your blood sugar and do not fail to use other medications given for blood sugar.

If you have venous disorder, especially varicose veins, you should keep your weight under control, avoid standing up for long periods and elevate your feet when you lie down. If your doctor has recommended certain exercises or protective stockings, follow these

recommendations. In these cases, it is necessary to follow these recommendations. It is not applicable to use X-VEN instead.

Do not use X-VEN in the following conditions

- Do not use if you are allergic to calcium dobesilate or to ingredients of X-VEN.

Take special care with X-VEN in the following conditions

- If you are on dialysis, use X-VEN only under significant medical supervision.
- If you have fever, infection of the oral cavity (tonsillitis), sore throat, inflammation of the genital area or related symptoms, stop taking X-VEN immediately and inform your doctor. Your doctor would order a blood count or other tests if necessary.
- X-VEN is for adult use only.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using X-VEN with food and drink

There is no interaction with food and drinks.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

X-VEN should not be used during pregnancy unless it is necessary.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking the medicine.

Calcium dobesilate is excreted into the breast milk in low quantities. Therefore, either the treatment or breast-feeding should be discontinued.

Effects on ability to drive and use of machines

It is unlikely to have an impact on the ability to drive and use of machines.

Important information about some of the excipients of X-VEN

There is no need for any warning for the excipients of X-VEN because of the method of administration or dose.

Using with other medicines

No data has yet been obtained on the interaction of X-VEN with other drugs.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to take X-VEN?

- **Instructions for appropriate method and dose/frequency of administration**

Always take it as prescribed by your doctor.

X-VEN is for adult use only.

Generally, 1 or 2 capsules should be taken once or twice a day with some water. Capsules should be ingested whole, with food.

In general, once or twice a day, 1 or 2 capsules should be taken with some water along with the food.

Maximum daily dose is 4 capsules.

Dosage and treatment duration are to be determined by the doctor based on the disease to be treated.

Your doctor will tell you how many times and how many capsules of X-VEN you will use.

Your doctor may recommend a higher or lower dosage depending on your response to treatment.

Do not exceed the recommended dose.

- **Route and method of administration:**

X-VEN is for oral use only.

The capsules should be swallowed whole with some water with meals, should not be chewed or opened.

- **Different age groups:**

Use in children:

There is currently insufficient data to recommend a dosage regimen for routine use in children (and adolescents under 18 years of age).

Use in elderly:

Use in elderly (aged 65 years and over) is exactly the same as in adults.

- **Special populations:**

Kidney/Liver Failure:

Dose should be reduced in dialysis patients with serious renal failure.

Your doctor will indicate how long your treatment should continue. Do not quit treatment prematurely, for stopping X-VEN treatment may worsen your disease.

If you have the impression that the effect of X-VEN is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more X-VEN than you should:

If you may have taken more X-VEN than you should, talk to a doctor or pharmacist.

If you forget to take X-VEN

Do not take double dose to make up for the dose you forgot.

If you have forgotten to take your medicine, take it as soon as you remember and take the next dose at the usual hour.

If you stop taking X-VEN

None.

4. Possible side effects

Like all medicines, side effects can occur in people sensitive to the contents of X-VEN.

If any of the following occur stop taking X-VEN and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Throat, intestine and other mucosal ulcers besides ulcers of skin, due to low white blood cell count.

These are all very serious side effects.

If you get any of these, this indicates you have serious hypersensitivity to X-VEN.

You may need emergency medical care or hospitalization.

Such serious side effects are very rare.

If you notice any of the following immediately inform your doctor or go to the nearest emergency department:

- Skin rash, fever, arthralgia

These are all serious side effects. They may require emergency medical treatment. Serious side effects occur very rarely.

Tell your doctor if you notice any of the following:

- Nausea
- Diarrhea
- Vomiting

These are mild side effects of X-VEN.

If these symptoms do not resolve spontaneously or if they are severe/irritating, contact your doctor.

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

5. How to store X-VEN?

Keep in the original package and out of the reach and sight of children.

Store below 25 °C at room temperature.

Take in accordance with the expiry date.

Take X-VEN before the expiry date indicated on the blister or package.

Do not use X-VEN if you notice any damage to the product and/or package.

Marketing authorization holder:

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This patient information leaflet was last approved on 15/11/2017.