DOXIUM® 500 CAPSULES

Calcium dobesilate 500mg

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What DOXIUM is used for

DOXIUM 500 is indicated in the following cases:

- Microangiopathies, in particular diabetic retinopathy. (Disorders of the small blood vessels of the retina in diabetic patients),
- Clinical signs of chronic venous insufficiency in the lower limbs (condition when the veins have problems sending blood from the leg to heart) with pain, cramps, paresthesia (tingling, pricking, chilling, burning or numb sensation on the skin) oedema (swelling), stasis dermatosis (skin inflammation)
- As adjuvant in superficial thrombophlebitis (infammatory condition of the veins due to a blood clot just below the surface of the skin)
- Haemorrhoids
- Micro-circulation disorders of arteriovenous origin (poor blood circulation from arteri and veins)

How DOXIUM works

Calcium dobesilate acts on small blood vessels – the capillaries – to normalise the resistance and permeability of their walls. It improves blood flow in the veins and, in disorders of the venous circulation, helps to reduce swelling of the ankles (oedema) and alleviates the pins and needles, pain and cramps.

Before you use DOXIUM

- When you must not take it

If you are allergic (hypersensitive) to calcium dobesilate or any of the other ingredients of DOXIUM 500.

During pregnancy and during breast-feeding.

DOXIUM 500 is not indicated for children.

- Before you start to take it

If you know or presume that you are pregnant ask your doctor or pharmacist for advice before taking any medicine.

If you suffer from kidney problems requiring dialysis, the dose should be reduced in these cases.

If you develop high fever, infections of the oral cavity, sore throat, anogenital inflammation and accompanying symptoms, you should immediately stop your treatment and inform your doctor. He/she will check your blood counts and take other measures if necessary.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Drugs may influence each other's effects.

At present no cases of interactions between DOXIUM 500 and other drugs have been confirmed.

DOXIUM 500 may interfere with
- certain blood test result
- creatinine enzyme measurement

How to take DOXIUM

- How much to take

The usual dose is 1capsule once or twice daily. The capsules should be taken orally with water or some other liquid and swallowed whole.

- When to take it

DOXIUM must to be taken during or immediately after main meals, in order to minimize any gastric discomfort.

- How long to take it

The duration of the treatment can be from a few weeks up to few months.
It must be adjusted individually, depending on the severity of the disease.

- If you forget to take it

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

- If you take too much (overdose)

Clinical symptoms of an accidental overdose are not known. It is recommended that you carefully observe the correct dosage. In the event of an overdose or accidental ingestion by a child, consult a doctor.

While you are using it

- Things you must do

Follow strictly the doctor's prescription, the method of use and instruction of the pharmacist who sold the medicinal product.

In the event of skin reaction, fever, joint pain or change in blood formula, you must stop the treatment immediately and inform your doctor because it may involve a hypersensitivity reaction.

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- Things you must not do

Do not by yourself interrupt the period of treatment prescribed for you.
Do not start to take this medicine again without consulting your doctor.

- Things to be careful of

If you suffer from severe kidney disease that may require dialysis therapy, the dose should be reduced.

If you develop high fever, infections of the oral cavity (including e.g. sore throat) or inflammatory changes in the anal and genital region, to discontinue the treatment in these cases

If you have serious allergic reactions symptoms could be signs of severe hypersensitive reactions, the treatment must be stopped.

Driving and using machines
This medicine may affect your ability to drive or use machines. If the capsules make you feel sick, nausea, headaches and fatigue, do not drive or use machines and contact your doctor immediately

Side effects

Like all medicines, DOXIUM 500 can cause side effects, although not everybody gets them.

Taking Doxium 500 can cause the following side effects : headache, gastrointestinal upsets, including abdominal pain, nausea, diarrhoea or vomiting, hepatobiliary disorder (liver problem) , joint pain, muscle pain, fever, shivering, weakness, fatigue, rash, allergic in skin, facial oedema, and in very rare cases, changes in blood counts (reduction of the number of white blood cells) and anaphylactic reaction. These reactions are generally spontaneously reversible after stopping the treatment.

With regard to the reduction of white blood cells and the signs (fever, infections of the oral cavity, sore throat, anogenital inflammation) that accompany this potentially serious disorder – very rarely observed with DOXIUM 500 – see above section "Before you start to take it".

In the event of gastrointestinal upsets, lowering of the dose or interruption of the treatment may be undertaken temporarily in agreement with your doctor.

In the event of skin reactions,fever, joint pain or change in blood formula, you must stop the treatment immediately and inform your doctor because it may involve a hypersensitivity reaction.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of DOXIUM

- Storage

Keep out of the reach and sight of children.

Do not use Doxium after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Store DOXIUM 500 at temperatures below 30ºC, in the original package to protect from humidity.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Hard gelatin capsule (cap: opaque dark green; body: opaque yellow) with a white powder fill.

Blister of 10 capsules with aluminum foil and a PVC/PVDC foil Cardboard boxes with 30 or 60 capsules.

- Ingredients

- Active substance:
  Calcium dobesilate 500 mg

- Inactive ingredients
  Magnesium stearate, maize starch. Capsule shell's composition: gelatin, yellow ferric oxide (E172), titanium dioxide (E171), Indigotin (E132)

- *MAL Number*
  MAL19970249AZ

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