

Paroven Capsules

Oxerutins 250 mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as your doctor has told you or as described in this leaflet.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

In this leaflet:

1. What Paroven Capsules are and what they are used for
2. What you need to know before you take Paroven Capsules
3. How to take Paroven Capsules
4. Possible side effects
5. How to store Paroven Capsules
6. Further information

1. WHAT PAROVEN CAPSULES ARE AND WHAT THEY ARE USED FOR

Paroven Capsules contain oxerutins as the active ingredient, which belongs to a group of medicines which act on small blood vessels (systemic vasoprotectors).

Paroven Capsules stabilise the vascular wall, which lead to a reduction in the permeability of the vessels and subsequently to a diminution of swelling (oedema).

Paroven Capsules relieve ankle swelling (oedema) due to chronic venous insufficiency (CVI). In patients with varicose veins and some other diseases of the leg veins, these small vessels have an excessive leakage which cause swelling of the ankles. Paroven Capsules also reduce this swelling and relieve the associated common symptoms such as aching, tired, heavy, swollen, painful and restless legs, pins and needles and night cramps.

It is recommended that such patients also wear elastic support (usually compression stockings) in CVI; in these cases, Paroven Capsules have been shown to produce additional benefit.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PAROVEN CAPSULES

Do not take Paroven Capsules if you are:

- allergic to oxerutins or any of the other ingredients of Paroven Capsules listed in Section 6.

Warnings and precautions

Do not take Paroven Capsules if you have lower leg swelling caused by heart, liver or kidney disease.

Children and adolescents

Paroven Capsules are not recommended in children and adolescents under 18 years of age as there is no data available.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

Taking Paroven Capsules with food and drink

The capsules can be taken with a drink or at mealtimes. There are no special requirements.

Pregnancy, breast-feeding and fertility

Paroven Capsules should not be used during the first three months of pregnancy. Do not use if you are pregnant, breast-feeding, think you might be pregnant or are planning to have a baby unless advised by your doctor.

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

Driving and using machines

Paroven Capsules have no influence on the ability to drive and use machines. If you experience tiredness or dizziness after using this product, do not drive or use machinery.

3. HOW TO TAKE PAROVEN CAPSULES

Always take Paroven Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Follow these instructions carefully.

The usual dose is as follows:

Adults over 18 years of age and the elderly

- Take 2 capsules (500 mg) twice a day.
- Swallow the capsules whole; do not crush or chew the capsules.
- Can be taken with or without food.

If no improvement in leg swelling is seen, please consult your doctor.

If you take more Paroven Capsules than you should

If you accidentally take too many Paroven Capsules, or suspect that a child has taken the capsules, contact your doctor or hospital casualty department immediately. Take the carton and capsules with you if possible.

If you forget to take Paroven Capsules

If you forget to take the capsules, take them as soon as possible unless it is time for the next dose. Do not take double the dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paroven can cause side effects, although not everybody gets them. The reactions are usually mild.

Stop taking the Capsules and tell your doctor immediately if you notice the following very rare symptoms:

- skin rash, swelling of the face, lips, tongue or throat
- hives
- difficulty breathing or swallowing

as these may be the first signs of an allergic reaction which may become severe

The side effects listed below have also been reported

Rare (may affect up to 1 in 1,000 people):

- Skin rashes with itching/scaling
- Gastrointestinal disorders, including (wind), diarrhoea, abdominal pain, stomach discomfort, dyspepsia (indigestion).

Very rare (may affect up to 1 in 10,000 people):

- allergic reactions (see advice above)
- dizziness, headache, flushing, tiredness, nausea, vomiting, photosensitivity reactions (reaction of the skin to sunlight), alopecia (hairloss), arthralgia (joint pain). These are usually mild and disappear rapidly on stopping treatment.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PAROVEN CAPSULES

Keep out of the sight and reach of children.

Protect from moisture and store in a dry place in the original pack.

Do not use Paroven Capsules after the expiry 'EXP' date which is stated on the blister and the carton. The 'EXP' date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Paroven Capsules contain

The active ingredient is oxicortin 250 mg

The other ingredients are polyethylene glycol, gelatin, titanium dioxide E171, shellac, yellow iron oxide E172, black iron oxide E172.

What Paroven Capsules look like and contents of the pack

Paroven Capsules are opaque, greyish-yellow in colour.

Paroven Capsules are available in blister packs of 120 capsules.

Marketing Authorisation Holder

Thornton & Ross Ltd.,
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HD7 5QH, UK.

Manufacturer

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For any information about this medicinal product, please contact the Marketing Authorisation Holder.

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