

# Paroven<sup>®</sup> 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

1. What Paroven Capsules are and what they are used for
2. Before you take Paroven Capsules
3. How to take Paroven Capsules
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## **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. 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 and at the end of Section 2.

### **Take special care with Paroven Capsules if you:**

- have lower leg swelling caused by heart, liver or kidney disease

If these conditions apply to you, please tell your doctor or pharmacist before taking Paroven Capsules.

### **Children and adolescents**

Paroven Capsules are not recommended in children.

### **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 and the Elderly

- Take 2 capsules (500 mg) twice a day.
  - Swallow the capsules whole; do not crush or chew the capsules.
  - Caps can be taken with or without food.
- If no improvement in leg swelling is seen, please consult your doctor.

### Children

Paroven Capsules are not recommended for children under 12 years of age.

### 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 (seen in less than 1 in 1000 people and in more than 1 in 10,000 people):

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

### Very rare (seen in less than 1 in 10,000 people and in more than 1 in 100,000 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. If any of the side effects gets serious, or if you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### If you get any other side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of suspect adverse reactions is an important way to continuously monitor the benefit/risk balance of the medicinal product in the real conditions of use. Healthcare professionals are asked to report any suspected adverse reaction via the Yellow Card Scheme, [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## 5. HOW TO STORE PAROVEN CAPSULES

Keep out of the reach and sight 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.

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.

## 6. FURTHER INFORMATION

### What Paroven Capsules contain

The active ingredient is oxeirtinib 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

Novartis Consumer Health  
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### Manufacturer

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