

Package Leaflet: Information for the patient
Ofcram SR 200mg Prolonged Release Capsules, Hard
Dipyridamole

Read all of this leaflet carefully before you start taking 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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Ofcram Prolonged Release Capsules are and what they are used for
2. What you need to know before you take Ofcram Prolonged Release Capsules
3. How to take Ofcram Prolonged Release Capsules
4. Possible side effects
5. How to store Ofcram Prolonged Release Capsules
6. Contents of the pack and other information

1. WHAT OFCRAM PROLONGED RELEASE CAPSULES ARE AND WHAT THEY ARE USED FOR

You must talk to your doctor if you do not feel better or if you feel worse after a few days.

Ofcram SR 200mg Prolonged Release Capsules (called Ofcram Prolonged Release Capsules throughout the rest of this leaflet) contain a medicine called dipyridamole. Ofcram belongs to a group of medicines called antithrombotic agents which are used to stop blood clots forming.

Ofcram Prolonged Release Capsules are used:

- After a stroke to prevent blood clots in the brain;
- To prevent blood clots forming after having a heart valve replaced.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OFCRAM PROLONGED RELEASE CAPSULES

Do not use Ofcram Prolonged Release Capsules:

- if you are allergic (hypersensitive) to dipyridamole, or any of the other ingredients in this medicine (listed in Section 6).

Warnings and Precautions

- Talk to your doctor or pharmacist before taking Ofcram Prolonged Release Capsules.

Take special care with Ofcram Prolonged Release Capsules:

Check with your doctor or pharmacist before taking your medicine if you have:

- Angina or other heart problems (including heart valve or circulation problems) or have recently had a heart attack;
- Myasthenia gravis (a rare muscle problem);
- Bleeding problems;
- Or if you are pregnant, planning to become pregnant or breast-feeding.

Always tell your doctor that you are taking Ofcram Prolonged Release Capsules before having a test of your heart function (myocardial imaging). Treatment with Ofcram Prolonged Release Capsules may affect the results. You may need to stop taking Ofcram Prolonged Release Capsules before you have the test.

Other medicines and Ofcram Prolonged Release Capsules

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, for example herbal medicine, strong vitamins and minerals.

Tell your doctor or pharmacist if you are taking medicines for:

- high blood pressure
- heart problems or irregular heartbeat (e.g. adenosine)
- blood clots (e.g. warfarin, aspirin)
- myasthenia gravis, a disease which causes muscle weakness (e.g. cholinesterase inhibitors).

Pregnancy, breast-feeding and fertility

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

Pregnancy

If you are pregnant you are not recommended to take Ofcram Prolonged Release Capsules. Ask your doctor for advice.

Breast-feeding.

If you are breast-feeding, do not take Ofcram Prolonged Release Capsules, as Ofcram is excreted into breast milk. Talk to your doctor.

Fertility

No data are available.

Driving and using machines

You may experience dizziness whilst taking Ofcram Prolonged Release Capsules. If this occurs you should not drive or operate machinery.

3. HOW TO TAKE OFCRAM PROLONGED RELEASE CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Use in adults

The recommended dose is one capsule twice daily, usually one in the morning and one in the evening.

The capsules should be swallowed whole without chewing.

Use in children

Ofcram Prolonged Release Capsules are not recommended in children.

If you take more Ofcram Prolonged Release Capsules than you should

Tell your doctor, hospital or pharmacist straight away if you have taken more Ofcram Prolonged Release Capsules than listed here or more than the doctor has prescribed and you feel unwell.

If you forget to take Ofcram Prolonged Release Capsules

If you forget a dose, take it as soon as you remember it. However, if it is time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ofcram Prolonged Release Capsules

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

Ofcram Prolonged Release Capsules with food, drink and alcohol

The capsules should be taken with food.

You should avoid alcohol when taking the capsules.

4. POSSIBLE SIDE EFFECTS

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

If you experience any of the following side effects after you have taken your medicine, see your doctor immediately. These side effects are rare but serious:

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and

makes breathing and swallowing difficult, stop taking your medicine and go to hospital straight away.

Very common (affects more than 1 in 10 patients)

- Headache;
- Feeling dizzy;
- Diarrhoea;
- Feeling sick.

Common (affects less than 1 in 10 patients to more than 1 in 100 patients)

- Worsening of the symptoms of heart disease such as chest pain;
- Being sick;
- Muscle pain.

Not known

- Increased heart rate;
- Lowering of blood pressure;
- Hot flushes;
- Tightening of the chest;
- Pale, raised, itchy areas of skin with red edges;
- A blood problem called “thrombocytopenia” which can cause bruising and prolong bleeding from wounds or during and after surgery;
- Gallstone pain (in the centre or right of your stomach).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRa Pharmacovigilance Section, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OFCRAM PROLONGED RELEASE CAPSULES

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

Do not store above 25°C.

Keep the container tightly closed in order to protect from moisture.

Do not open the container until you are ready to start taking the capsules. If you have any capsules left after six weeks, these should not be taken.

Do not use this medicine after the expiry date which is stated on the carton. The expiry 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ofcram Prolonged Release Capsules contain

The active substance is dipyridamole. Each capsule contains dipyridamole 200mg.

The other ingredients are:

Tartaric acid pellets

Hypromellose E 15

Talc

Acacia, spray-dried

Triacetin

Povidone (PVP K30)

Simeticone Emulsion (30 % W/V)

Methacrylic acid - ethyl acrylate copolymer

Hypromellose phthalate P55

Capsule shells:

Gelatin

Titanium dioxide (E171)

Red and yellow iron oxides (E172)

What Ofcram Prolonged Release Capsules look like and contents of the pack

Hard gelatin capsules consisting of a red cap and an orange body. Dimension 7,66 mm x 23,1 mm.

The capsule contains yellow coloured slow release pellets.

HDPE bottle with polypropylene child resistant closure, containing 1 desiccant.

Packs contain 60 capsules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:

Focus Pharmaceuticals Limited, Capital House, 1st Floor, 85 King William Street,
London EC4N 7BL, UK

Tel: 00 44 (0)1283 495 280 Fax: 00 44 (0)1283 495 290

Email: medinfo@focuspharma.co.uk

The Manufacturer is:

Geryon Pharma Limited, 18 Owen Drive, Liverpool, L24 1YL, UK

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

Other sources of information

**For information in large print, audio CD or Braille please
telephone 00 44 (0)1283 495 280 or email
medinfo@focuspharma.co.uk.**

This leaflet was last revised in 12/2015.