

Selectol[®] 200mg Film-coated Tablets

(celiprolol hydrochloride)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine

- * Keep this leaflet. You may need to read it again.
- * If you have further questions, ask your doctor or your pharmacist.
- * This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.
- * 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.

In this leaflet:

- 1 What Selectol is and what it is used for
- 2 What you need to know before you take Selectol
- 3 How to take Selectol
- 4 Possible side effects
- 5 How to store Selectol
- 6 Contents of the pack and other information

1 What Selectol is and what it is used for

What Selectol is

The name of your medicine is Selectol 200mg Tablets (called Selectol throughout this leaflet). Selectol contains a medicine called celiprolol hydrochloride. This belongs to a group of medicines called beta-blockers.

How Selectol works

It works by slowing your heart rate or lowering your blood pressure.

Selectol can be used to

It is used to treat high blood pressure (hypertension) and chest pain (angina).

2 What you need to know before you take Selectol

Do not take this medicine and tell your doctor if:

- * You are allergic (hypersensitive) to celiprolol or any of the other ingredients in Selectol (see Section 6: Contents of the pack and other information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- * You have or have had episodes of asthma or wheezing
- * You have a very slow heart beat (bradycardia) or low blood pressure (hypotension)
- * You have heart problems – such as a condition where there is an impairment with the heart's ability to conduct electrical impulses, if your heart is not pumping blood as well as it should do, abnormal heart rhythm, difficulty breathing and swollen ankles
- * A condition which results in a tumour of the adrenal gland (phaeochromocytoma)
- * You have late stage peripheral arterial occlusive disease or Raynaud's syndrome

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Selectol.

Warnings and precautions

Take special care and check with your doctor or pharmacist before taking Selectol if:

- * You have any heart problems such as disease of the arteries (ischaemic heart disease), a condition whereby your heart cannot pump a sufficient supply of blood (cardiac or congestive heart failure), impairment with heart's ability to conduct electrical impulses (1st degree heart block),
 - * You suffer from a type of chest pain called Prinzmetal's angina
 - * You have asthma or breathing problems due to long term lung problems (called bronchitis or emphysema)
 - * You have diabetes
 - * You have kidney problems
 - * You have liver problems
 - * You have a history of severe allergies particularly to other medicines
 - * You have an over active thyroid. This medicine may mask the signs of an over active thyroid
 - * You suffer from very poor circulation (such as Raynaud's disease). Symptoms include fingers and toes changing colour when cold and tingling or painful on warming up
 - * You have psoriasis, as this medicine may make it worse
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Selectol. Do this even if they applied only in the past.

Children

Selectol is not recommended for use in children.

Operations or anaesthetics

Tell your doctor or dentist you are taking Selectol if you are going to have an anaesthetic or an operation (including dental surgery).

Taking Selectol with 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, including herbal medicines.

This is because Selectol can affect the way some other medicines work. Also, some other medicines can affect the way Selectol works.

Tell your doctor if you are taking any of the following:

- * Insulin or tablets to treat diabetes
- * Medicines used for mental problems (antipsychotic medicines) – such as tricyclic depressants, monoamine oxidase inhibitors and phenothiazines.
- * Medicines used for asthma
- * Medicines used as anaesthetics
- * Medicines for chest pain (angina) - such as verapamil, nifedipine and diltiazem
- * Medicines used for heart problems - amiodarone, digitalis, diltiazem, nifedipine, disopyramide, quinidine, bepridil and verapamil (also used for severe allergies)
- * Medicines used for high blood pressure such as clonidine
- * Medicines used to relieve pain such as Non-Steroidal Anti-inflammatory Drugs (NSAIDs) e.g. Floctafenine, ibuprofen, indomethacin.
- * Medicines used for the prevention of malaria such as mefloquine
- * Medicines such as verapamil, erythromycin, clarithromycin, ciclosporin, quinidine, ketokonazole, itraconazole, rifampicin and St. John's wort, which may affect the amount of this medicine you absorb

If you are not sure, talk to your doctor or pharmacist before taking Selectol.

Taking Selectol with food and drink

- * Selectol should be taken preferably first thing in the morning, 60 minutes before food or two hours after a meal.
- * Citrus juices increase the amount of Selectol that you absorb, so should be avoided while taking this medicine

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Selectol should not be used during pregnancy unless there is no safer alternative. If you take Selectol during pregnancy, you should tell your midwife. This is because your baby may be affected when it is born. These effects can include slow heart beat, heart failure or having trouble breathing. If your baby has any of these side effects when it is born and you are worried, tell your doctor or midwife.

You should not breast-feed if you are taking Selectol.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel tired or dizzy or experience tremor, headaches or impaired vision, whilst taking Selectol. If this happens, do not drive or use any tools or machines.

Drug Tests

Selectol may give a positive result if you have a blood or urine test to check for the presence of drugs.

3 How to take Selectol

Always take Selectol exactly as your doctor has told you. The dose of Selectol will depend on your needs and the illness being treated. Check with your doctor or pharmacist before taking Selectol.

Taking this medicine

- * Swallow the tablets whole with a drink of water
- * Take the tablets preferably first thing in the morning, 60 minutes before food, or 2 hours after a meal
- * Take your medicine at the same time each day preferably first thing in the morning.

How much to take

Adults

- * The usual starting dose is 200mg once daily
- * The maximum dose is 400mg once daily.

Selectol® 200mg Film-coated Tablets

Ref: 048/001/200715/1/B

(celiprolol hydrochloride)

Patient Information Leaflet (continued)

Children

Selectol should not be given to children.

Elderly patients and patients with kidney problems

Your doctor may decide to lower your dose of Selectol if necessary.

If you take more Selectol than you should

Tell your doctor or go to the nearest hospital casualty department straight away. Remember to take with you any tablets that are left and the pack. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, difficulty breathing or wheezing.

If you forget to take Selectol

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose.

Stopping treatment

Keep taking your medicine until your doctor tells you to stop. Do not stop taking Selectol just because you feel better. If you stop taking Selectol, your illness may get worse. When your doctor says that you can stop taking Selectol, you need to do this gradually, over 1-2 weeks. Your doctor will help you do this. If you have any further questions about this medicine, ask your doctor or pharmacist.

4 Possible side effects

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

Tell your doctor straight away if you experience any of the following:

- * Allergic reaction: Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- * Skin rashes
- * You get flu-like symptoms, swollen or painful joints, increased sensitivity to sunlight, hairloss, abdominal pain, anaemia. This may mean you have a condition called Systemic Lupus Erythematosus (SLE).
- * Changes in behaviour, depression
- * Problems with your eyesight such as blurred vision
- * Pain in your chest and feeling weak or dizzy. These could be signs of a heart problem
- * Slow heart rate or very fast, uneven or forceful heartbeat (palpitations)
- * Breathing problems such as asthma, tightening of chest (bronchospasm), difficulty breathing, inflammation of the lung (interstitial pneumonitis).

Tell your doctor as soon as possible if you experience any of the following:

- * Feeling dizzy, light-headed or, weak. These could be signs of low blood pressure.
- * Stomach pain, diarrhoea, feeling sick or being sick
- * Difficulty sleeping, drowsiness, nightmares or hallucinations
- * Dryness of the eye or mouth
- * Hot flushes or excessive sweating
- * Shakiness (tremor)
- * Low blood sugar levels (hypoglycaemia).
- * High blood sugar levels (hyperglycaemia).
- * Headache
- * A cold or numb feeling in your fingers or toes (Raynaud's disease or syndrome)
- * Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- * Difficulty in getting or maintaining an erection, or in ejaculating (impotence)
- * Lack of interest in sexual activities (libido)
- * Changes in liver enzymes
- * Tiredness

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, HPRAs Pharmacovigilance, 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 Selectol

- * Keep out of the sight and reach of children
- * Do not use Selectol after the expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month
- * Store below 25°C
- * Store in the original package
- * 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 Contents of the pack and other information

What Selectol contains

Each tablet contains 200mg of celiprolol hydrochloride as the active substance. Each tablet also contains mannitol, microcrystalline Cellulose, croscarmellose sodium and magnesium stearate.

The film coating contains Opadry Y-1R-7000 (Hyromellose, polyethylene glycol, titanium dioxide) and Opadry YS-1-7006 (Hyromellose and polyethylene glycol).

What Selectol looks like and the contents of the pack

Selectol Tablets 200mg are white film coated, heart shaped tablets, engraved with a distinctive heart logo on one side, '200' and bisect line on the other. Selectol tablets are supplied in blister packs of 28 tablets.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Manufactured by:

Sanofi Winthrop Industrie, 56 Route de Choisy au Bac, 60205 Compiègne, France.

Selectol is a registered trademark of Aventisub II Inc.

Leaflet revision date: 20/07/2015

POM PPA1562/048/001

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.