

Sectral® 200mg

acebutolol

Film-coated tablets

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 any questions or if you are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally. 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Sectral 200 mg film-coated tablets are and what they are taken for
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1. WHAT Sectral 200 mg film-coated tablets ARE AND WHAT THEY ARE TAKEN FOR

Pharmacotherapeutic group: SELECTIVE BETA-BLOCKER

This medicine is a beta-blocker. It decreases certain effects (the so-called "beta" effects) of the sympathetic system that controls heart function and blood circulation.

This medicine is recommended for use in

- High blood pressure
- Some heart rate disorders
- Prevention of painful effort angina attacks
- Long-term treatment after myocardial infarction

2. BEFORE YOU TAKE Sectral 200 mg film-coated tablets

If your doctor has told you that you are intolerant to some kinds of sugar, contact him/her before taking this medicine.

Never take Sectral 200 mg film-coated tablets in the following situations:

- severe asthma and severe chronic obstructive pulmonary disease (COPD) (*bad asthma and bronchial/lung disease with congestion*)
- heart failure not controlled by treatment (*heart function problems not controlled by treatment*)
- cardiogenic shock (shock caused by heart problems)
- second and third degree atrioventricular block in unpaced patients (*particular heart conduction problems*)
- variant angina (in its typical form and as single-agent therapy) (*a type of angina attack*)
- sinus node disease (including sinoatrial block)
- severe bradycardia (<45-50 beats per minute) (*a very slow heartbeat*)
- severe Raynaud's disease and severe peripheral arterial disorders (*severe circulation problems and numbness in the fingers of both hands and problems in the arteries of the limbs*)
- untreated pheochromocytoma (*growth on the adrenal gland secreting substances that cause severe high blood pressure*)
- hypotension (*decreased blood pressure*)
- hypersensitivity to acebutolol
- history of anaphylactic reaction (*previous allergic reaction*)
- breast-feeding
- in combination with floctafenine (*pain medicine*)
- if you are allergic (hypersensitive) to wheat, as this medicine contains wheat starch.

You must not take this medicine, in general, with bepridil, diltiazem, verapamil (*medicines for the heart*).

Take special care with Sectral 200 mg film-coated tablets:

Special warnings

This medicine contains lactose. It is not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption syndrome. NEVER DISCONTINUE TREATMENT SUDDENLY WITHOUT FIRST SEEKING MEDICAL ADVICE.

KEEP OUT OF THE REACH OF CHILDREN.

Precautions when taking Sectral 200 mg film-coated tablets

Inform your doctor if you are pregnant, diabetic, have kidney or liver failure, psoriasis, a history of allergies or certain diseases of the arteries (Raynaud's disease). If you need to have surgery, tell the anesthesiologist that you are taking this medicine.

You can take this medicine if you have celiac disease. Wheat starch may contain gluten, but only in traces, and it is therefore not considered to be a danger for patients with celiac disease.

Taking/using other medicines

If you are taking or have recently taken another medicine, particularly bepridil, diltiazem or verapamil, or a medicine obtained without a prescription, talk to your doctor or pharmacist.

Pregnancy and breast-feeding

Pregnancy

If needed, this medicine can be taken during pregnancy.

If the treatment is taken at the end of pregnancy, medical monitoring of the newborn will be required for a few days, as some of the effects of treatment can also occur in the child.

Breast-feeding

A large amount of this medicine passes into breast milk. Breast-feeding is therefore contraindicated in women taking this treatment.

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

Athletes

The attention of athletes is drawn to the fact that this medicine contains a drug substance that may induce a positive result in doping tests.

Important information about some of the ingredients of Sectral 200 mg film-coated tablets

List of excipients with specific effects: lactose, wheat starch (gluten).

3. HOW TO TAKE Sectral 200 mg film-coated tablets

How many Sectral 200 mg film-coated tablets should be taken

Always comply with the dosage prescribed by your doctor.

If you are unsure of anything, ask your doctor or pharmacist.

Dosage varies depending on the disorder being treated and it is also adapted to each patient.

How Sectral 200 mg film-coated tablets should be taken

Oral route.

The tablets are to be swallowed with a drink without chewing.

How often Sectral 200 mg film-coated tablets should be taken

In all cases, strictly comply with your doctor's prescription.

How long Sectral 200 mg film-coated tablets should be taken for

In most disorders, beta-blocker treatment continues for several months or years.

Your doctor will tell you how long to take the treatment for.

If you have taken more Sectral 200 mg film-coated tablets than you should

Inform your doctor or hospital.

If you forget to take Sectral 200 mg film-coated tablets

If you forget a tablet, take it as soon as possible and continue treatment as normal. Do not take a double dose to make up for a forgotten dose.

If you have any questions about taking this medicine, ask your doctor or pharmacist for more information.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sectral 200 mg film-coated tablets can cause side effects, although not everybody gets them:

- Most frequent: tendency to tire, cooling of hands and feet, slow pulse, gastrointestinal disorders, impotence.
 - Far more rare: significant slowing of the heart, heart failure, drop in blood pressure, difficulty breathing, hypoglycemia (*not enough blood sugar*), Raynaud's syndrome, worsening of existing intermittent claudication (*difficulty walking*), various skin effects, particularly rashes resembling psoriasis or worsening of psoriasis.
 - Exceptional: pneumopathy of immune-allergic origin (lung disease), immunological problems (appearance of antinuclear antibodies) possibly leading to lupus.
- If you notice any side effects not listed in this leaflet or if any of the side effects becomes serious, please tell your doctor or pharmacist.

5. HOW TO STORE Sectral 200 mg film-coated tablets

Keep out of the reach and sight of children.

Do not use Sectral 200 mg film-coated tablets after the expiry date stated on the box. Store at a temperature not exceeding 25°C.

Medicines must 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 Sectral 200 mg film-coated tablets contain

The active substance is:

acebutolol hydrochloride.....	221.70 mg
Equivalent quantity of acebutolol.....	200.00 mg

for one film-coated tablet.

The other ingredients are:

Lactose, wheat starch, talc, anhydrous colloidal silica, polyvidone, magnesium stearate, hypromellose, macrogol 20 000.

How Sectral 200 mg film-coated tablets are supplied and contents of the pack

This medicine is supplied as film-coated tablets. Box of 30.

Marketing Authorization Holder and operating company

sandoz-aventis France

1-13, boulevard Romain Rolland
75014 Paris, France.

Manufacturer

Famar Lyon
29 avenue Charles de Gaulle
69230 Saint-Genis-Laval, France.

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