

Sectral® 400mg Tablets

(acebutolol hydrochloride)

3310
06.04.24[5]

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 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your medicine is available using the above name but will be referred to as Sectral throughout this leaflet. This medicine is also available in other strengths and form.

In this leaflet:

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

1. WHAT SECTRAL IS AND WHAT IT IS USED FOR

The name of your medicine is Sectral 400 mg Tablets. This belongs to a group of medicines called beta-blockers. It works by slowing your heart rate or lowering your blood pressure.

Sectral is used for:

- Chest pain (angina)
- High blood pressure
- Uneven or unusually fast heart beats (arrhythmia)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SECTRAL

Do not take Sectral:

- if you are allergic to acebutolol hydrochloride, other beta-blockers or any of the other ingredients of this medicine (listed in section 6) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have low blood pressure
- if you have severe heart problems or heart failure not controlled by medicines
- if you have a very slow heartbeat - less than 50 beats per minute
- if your doctor has told you that you have an abnormal level of acid in your blood (called acidosis)
- if you have serious blood circulation problems
- if you have a tumour on the adrenal gland (called pheochromocytoma)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Sectral:

- if you have kidney problems
- if you have heart failure that is controlled with medicines
- if you have a slow heart beat (also see section 'Do not take Sectral')
- if you have breathing problems due to long term lung problems (called 'asthma', 'bronchitis' or 'emphysema')
- if you have an overactive thyroid gland
- if you have diabetes or low blood sugar levels (hypoglycaemia)
- if you have psoriasis
- if you have mild or moderate blood circulation problems. You may have cold hands and feet that look darker than the rest of your body
- if you have a form of chest pain known as 'Prinzmetal's' angina
- if you have a history of allergies

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sectral.

Operations or anaesthetics

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

Other medicines and Sectral

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Sectral can affect the way some other medicines work. Also some medicines can affect the way Sectral works.

In particular, tell your doctor if you are taking any of the following:

- Other medicines for high blood pressure
- Clonidine used for migraine or high blood pressure. If you are taking clonidine and Sectral together, you should not stop taking clonidine unless your doctor tells you. If you have to stop taking clonidine, your doctor will give you instructions
- Medicines for chest pain (angina) such as verapamil, nifedipine or diltiazem. Verapamil must not be taken within several days of taking Sectral

- Medicines for heart problems such as amiodarone, disopyramide or digoxin
- Medicines used for mental health problems (antipsychotic medicines) – such as haloperidol, sulpiride, pimozide or flupenthixol
- Some medicines used for depression (mono-amine oxidase inhibitors or tricyclic antidepressants) such as phenelzine, imipramine or amitriptyline
- Medicines to help you sleep (barbiturates) such as amobarbital
- Insulin or tablets to treat diabetes – such as glibenclamide. Your doctor may change your dose
- Medicines used for breathing problems - such as aminophylline, theophylline, salbutamol and terbutaline
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) – used to relieve pain (such as ibuprofen, naproxen, diclofenac, indometacin and piroxicam)
- Fingolimod used for treating multiple sclerosis. Your doctor may perform monitoring at the start of treatment
- Diltiazem as it may lead to increased risk of depression.

Sectral with food

Take Sectral with or just after meals

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. Sectral should not normally be given during pregnancy as it may cause problems with the foetus or newly born baby.
- You are breast-feeding or planning to breast-feed. You should not breast-feed if you are taking Sectral. This is because small amounts may pass into mothers' milk.
- Beta-blockers can reduce blood flow to the placenta, which can result in premature birth, newborn smaller than expected, intrauterine foetal death and abortion.

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 while taking this medicine. If this happens, do not drive or use any tools or machines.

Sectral contains:

- **Lactose.** This medicine contains lactose, a type of sugar. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking Sectral Tablets.
- **Wheat starch.** This medicine contains only very low levels of gluten (from wheat starch). It is regarded as "gluten free" and is very unlikely to cause problems if you have coeliac disease. One tablet contains no more than 3.94 micrograms of gluten. If you have wheat allergy (different from coeliac disease), you should not take this medicine.

3. HOW TO TAKE SECTRAL

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

The recommended dose is:

Adults (including the elderly)

The usual dose of Sectral depends on your needs and the illness being treated. Your doctor will advise you.

Chest pains (angina)

- The starting dose is 400mg once a day at breakfast or 200mg twice a day
- If necessary, your doctor may increase this to 300mg three times a day
- The maximum daily dose is 1200mg

High blood pressure

- The starting dose is 400mg once a day at breakfast or 200mg twice a day
- If necessary, after 2 weeks, your doctor may increase this to 400mg twice a day

Uneven or unusually fast heart beats (arrhythmia)

- The starting dose is 200mg daily
- If necessary, your doctor may increase this to 400mg to 1200mg daily

Patients with kidney problems

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

If you take more Sectral than you should

If you take more tablets than you should

- Tell a doctor or go to a hospital casualty department straight away.
- Take the medicine pack with you. This is so the doctors know what you have taken.
- The following effects may happen:
Feeling dizzy or weak, difficulty in breathing or wheezing, low blood sugar or serious heart problems.

If you forget to take Sectral

If you forget a dose, take it as soon as you remember it. However, if it is nearly 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 Sectral

Keep taking Sectral until your doctor tells you to stop. If you stop treatment suddenly your illness may get worse. When your doctor says that you can stop taking Sectral, you need to do this gradually. 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, this medicine can cause side effects, although not everybody gets them.

Stop taking Sectral and see your doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side-effects:

Very common (affects more than 1 person in 10)

- Blood tests may show changes to your immune system. Signs may include joint aches and pains, swollen joints, increased sensitivity to sunlight, mouth ulcers, hair loss, anxiety, fevers, night sweats and stomach pain.

Common (affects less than 1 person in 10)

- Changes in behaviour or depression, nightmares
- Pain in your chest and feeling weak or dizzy. These could be signs of heart problems or low blood pressure.
- Blurred vision
- Shortness of breath or difficulty in breathing, cough, tiredness, fainting. These could be signs of inflammation in your lungs.

Other side effects include:

- Seeing or hearing things that are not there (hallucinations), confusion
- Difficulty in sleeping (insomnia)
- Dry eyes
- Slow heart rate. Swelling of feet or ankles. These could be signs that your heart is not working properly
- Episodes of muscle cramps or muscle pain especially when you walk or exercise
- Fingers and toes changing colour when cold and tingling or painful on warming up. This could be Raynaud's phenomenon.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days.

Very common (affects more than 1 person in 10)

- Lethargy

Common (affects less than 1 person in 10)

- Diarrhoea, feeling sick (nausea), headache

Other side effects include:

- Lack of interest in sexual activities (loss of libido)
- Being sick (vomiting)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)

Not known (frequency cannot be estimated from the available data)

- Hair loss (Alopecia)

Blood tests

Sectral can increase the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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 at: 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 SECTRAL

Keep out of the sight and reach of children.

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

If the tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

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 Sectral contains

The active ingredient is acebutolol hydrochloride.

- Each tablet contains 400mg of acebutolol (as hydrochloride).
- The other ingredients are lactose monohydrate, wheat starch, talc, silica colloidal anhydrous, povidone, magnesium stearate, hypromellose and macrogol 20 000.

What Sectral looks like and contents of the pack

The tablets are film-coated, white, oblong, marked RPR and 114 on either side of a breakline on one side and plain on the other side.

They are available in blister packs of 30 and 100 tablets.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by

Sanofi Aventis SA, Carretera C-35 La Batlloria-Hostalric Km 63.09, Riells I Viabrea, Girona E-17404, Spain.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the
leaflet in a format suitable for you.**

Acebutolol 400mg film-coated tablets

(acebutolol hydrochloride)

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- 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.

Your medicine is available using the above name but will be referred to as Acebutolol throughout this leaflet. This medicine is also available in other strengths and form.

In this leaflet:

1. What Acebutolol is and what it is used for
2. What you need to know before you take Acebutolol
3. How to take Acebutolol
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1. WHAT ACEBUTOLOL IS AND WHAT IT IS USED FOR

The name of your medicine is Acebutolol 400 mg Tablets. This belongs to a group of medicines called beta-blockers. It works by slowing your heart rate or lowering your blood pressure.

Acebutolol is used for:

- Chest pain (angina)
- High blood pressure
- Uneven or unusually fast heart beats (arrhythmia)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACEBUTOLOL

Do not take Acebutolol:

- if you are allergic to acebutolol hydrochloride, other beta-blockers or any of the other ingredients of this medicine (listed in section 6) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have low blood pressure
- if you have severe heart problems or heart failure not controlled by medicines
- if you have a very slow heartbeat - less than 50 beats per minute
- if your doctor has told you that you have an abnormal level of acid in your blood (called acidosis)
- if you have serious blood circulation problems
- if you have a tumour on the adrenal gland (called pheochromocytoma)

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Acebutolol:

- if you have kidney problems
- if you have heart failure that is controlled with medicines
- if you have a slow heart beat (also see section 'Do not take Acebutolol')
- if you have breathing problems due to long term lung problems (called 'asthma', 'bronchitis' or 'emphysema')
- if you have an overactive thyroid gland
- if you have diabetes or low blood sugar levels (hypoglycaemia)
- if you have psoriasis
- if you have mild or moderate blood circulation problems. You may have cold hands and feet that look darker than the rest of your body
- if you have a form of chest pain known as 'Prinzmetal's' angina
- if you have a history of allergies

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Acebutolol.

Operations or anaesthetics

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

Other medicines and Acebutolol

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In particular, tell your doctor if you are taking any of the following:

- Other medicines for high blood pressure
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- Some medicines used for depression (mono-amine oxidase inhibitors or tricyclic antidepressants) such as phenelzine, imipramine or amitriptyline
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- Fingolimod used for treating multiple sclerosis. Your doctor may perform monitoring at the start of treatment
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Acebutolol with food

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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. Acebutolol should not normally be given during pregnancy as it may cause problems with the foetus or newly born baby.
- You are breast-feeding or planning to breast-feed. You should not breast-feed if you are taking Acebutolol. This is because small amounts may pass into mothers' milk.
- Beta-blockers can reduce blood flow to the placenta, which can result in premature birth, newborn smaller than expected, intrauterine foetal death and abortion.

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 while taking this medicine. If this happens, do not drive or use any tools or machines.

Acebutolol contains:

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- **Wheat starch.** This medicine contains only very low levels of gluten (from wheat starch). It is regarded as "gluten free" and is very unlikely to cause problems if you have coeliac disease. One tablet contains no more than 3.94 micrograms of gluten. If you have wheat allergy (different from coeliac disease), you should not take this medicine.

3. HOW TO TAKE ACEBUTOLOL

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Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

The recommended dose is:

Adults (including the elderly)

The usual dose of Acebutolol depends on your needs and the illness being treated. Your doctor will advise you.

Chest pains (angina)

- The starting dose is 400mg once a day at breakfast or 200mg twice a day
- If necessary, your doctor may increase this to 300mg three times a day
- The maximum daily dose is 1200mg

High blood pressure

- The starting dose is 400mg once a day at breakfast or 200mg twice a day
- If necessary, after 2 weeks, your doctor may increase this to 400mg twice a day

Uneven or unusually fast heart beats (arrhythmia)

- The starting dose is 200mg daily
- If necessary, your doctor may increase this to 400mg to 1200mg daily

Patients with kidney problems

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

If you take more Acebutolol than you should

If you take more tablets than you should

- Tell a doctor or go to a hospital casualty department straight away.
- Take the medicine pack with you. This is so the doctors know what you have taken.
- The following effects may happen:
Feeling dizzy or weak, difficulty in breathing or wheezing, low blood sugar or serious heart problems.

If you forget to take Acebutolol

If you forget a dose, take it as soon as you remember it. However, if it is nearly 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 Acebutolol

Keep taking Acebutolol until your doctor tells you to stop. If you stop treatment suddenly your illness may get worse. When your doctor says that you can stop taking Acebutolol, you need to do this gradually. 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

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Stop taking Acebutolol and see your doctor or go to a hospital straight away if:

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Tell your doctor as soon as possible if you have any of the following side-effects:

Very common (affects more than 1 person in 10)

- Blood tests may show changes to your immune system. Signs may include joint aches and pains, swollen joints, increased sensitivity to sunlight, mouth ulcers, hair loss, anxiety, fevers, night sweats and stomach pain.

Common (affects less than 1 person in 10)

- Changes in behaviour or depression, nightmares
- Pain in your chest and feeling weak or dizzy. These could be signs of heart problems or low blood pressure.
- Blurred vision
- Shortness of breath or difficulty in breathing, cough, tiredness, fainting. These could be signs of inflammation in your lungs.

Other side effects include:

- Seeing or hearing things that are not there (hallucinations), confusion
- Difficulty in sleeping (insomnia)
- Dry eyes
- Slow heart rate. Swelling of feet or ankles. These could be signs that your heart is not working properly
- Episodes of muscle cramps or muscle pain especially when you walk or exercise
- Fingers and toes changing colour when cold and tingling or painful on warming up. This could be Raynaud's phenomenon.

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Very common (affects more than 1 person in 10)

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Common (affects less than 1 person in 10)

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Other side effects include:

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- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)

Not known (frequency cannot be estimated from the available data)

- Hair loss (Alopecia)

Blood tests

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Reporting of side effects

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