

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sibelium® 5 mg Tablets

flunarizine

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. WHAT SIBELIUM IS AND WHAT IT IS USED FOR

What is Sibelium?

Sibelium tablets contain flunarizine. They belong to a group of medicines known as calcium channel blockers, which work by preventing the narrowing of blood vessels.

What is it used for?

Sibelium Tablets are for use in adults.

They have been prescribed for you to help your migraine-type headaches. If you take Sibelium Tablets regularly they can help you get fewer headaches, or less painful headaches. They can stop some migraine attacks starting and help make other attacks less severe. While you are taking Sibelium Tablets, your doctor will review your treatment at regular intervals in order to assess your response to the medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SIBELIUM

Do not take Sibelium

- if you are allergic (hypersensitive) to flunarizine or any of the other ingredients of Sibelium Tablets (listed in Section 6 below)
- if you have a depressive illness or have a history of recurrent depression.
- if you have Parkinson's Disease or a similar disease.

Warnings and precautions

- Talk to your doctor or pharmacist before taking Sibelium Tablets if;
- you start to feel tired while taking the tablets, tell your doctor as this can be an effect of the tablets. Your doctor may stop your treatment, or reduce your dose.
- you take more tablets than recommended, this will increase the risk of side effects.
- Women who have had depressive illness may be more likely to become depressed again when using this medicine long term.
- you are elderly, as the tablets may give rise to depressive illness, Parkinson's Disease or a similar disease.

Other medicines and Sibelium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal products. In particular, tell them if you are taking;

- medicines for anxiety or to help you sleep (tranquillisers), as Sibelium Tablets may make you feel more drowsy.
- an oral contraceptive, as you may secrete breast milk in the first two months of treatment.
- medicine to control high blood pressure, your doctor may adjust the dosage of this while you are taking Sibelium Tablets.

If you think your medicine has affected you in any other way, tell your doctor.

Sibelium with alcohol

Don't drink alcohol while taking Sibelium Tablets.

The combined effect of Sibelium Tablets and alcohol can make you feel drowsy.

Pregnancy and breast-feeding

Talk to your doctor before using Sibelium Tablets if you are pregnant or trying to become pregnant. Sibelium tablets are not recommended during pregnancy. Do not breast-feed if you are taking Sibelium Tablets, as small amounts of the medicine could pass into your milk.

Driving and using machines

Sibelium Tablets can make you drowsy. If this happens, do not drive or use any tools or machines.

Sibelium Tablets contain lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking Sibelium Tablets.

This medicine contains less than 1 mmol sodium (23 mg) in each tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE SIBELIUM

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

Always take Sibelium Tablets after a meal whenever possible to avoid stomach irritation. Swallow the tablets whole with water.

Your doctor will tell you how many Sibelium Tablets to take and how long to take them for. Always read the label on your medicine and follow your doctor's instructions carefully. Ask your pharmacist if you are not sure about anything.

The recommended dose is:

Patients aged 18 to 64 years:

Take two Sibelium Tablets in the evening.

Patients aged 65 years and older:

Take one Sibelium Tablet in the evening.

Children:

Sibelium Tablets are not recommended for use in children.

On-going treatment

After taking Sibelium Tablets for a while your doctor may recommend that you have two successive "tablet-free" days each week- e.g. Saturday and Sunday.
After 6 months take a complete break from Sibelium Tablets

If you take more Sibelium than you should

If you, or anyone else, takes more Sibelium Tablets than you were told to, contact a doctor or local hospital immediately.

If you forget to take Sibelium

If you forget to take your medicine, do not take the missed dose. Wait and take your next dose as usual, then continue your course of medicine.

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of 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.

Tell your doctor as soon as possible if you notice or suspect any of the following. You may need medical treatment.

- Tingling or numbness in the hands or feet (affects fewer than 1 in 100 people)
- Buzzing, hissing, whistling, or ringing noise in the ears (tinnitus) (affects fewer than 1 in 100 people)
- Jerky movements and problems such as slowness, muscle stiffness or rigidity and trembling. Twitching or unusual movements of the tongue, face, mouth, jaw or throat. If you get any of these effects, you may be given an additional medicine (the frequency is not known)
- Severe allergic reaction causing a swollen face, lips, mouth, tongue or throat, which may lead to difficulty swallowing or breathing (the frequency is not known)

Very Common side effects (affects more than 1 in 10 people)

- Increase in body weight

Common side effects (affects fewer than 1 in 10 people)

- Increased appetite
- Blocked or runny nose
- Feeling low or depressed
- Problems with sleeping or feeling sleepy
- Feeling sick
- Constipation
- Stomach ache or other digestive problems
- Muscle aches
- Pain in the breasts
- Menstrual problems such as irregular periods
- Feeling tired

Uncommon side-effects (affects fewer than 1 in 100 people)

- Feeling uninterested or anxious, restless, weak or lacking energy
- Feeling disorientated
- Blockage in the gut

- Indigestion
- Vomiting
- Awareness of unusual heart beats
- Low blood pressure
- Muscle twitches or spasms; twisted neck
- Swollen breasts
- Unusually heavy periods or scanty periods
- Lack of sex drive
- Swelling in the hands, legs, feet or other parts of the body
- Dry mouth
- Excessive sweating
- Allergic reaction, skin rash, flushing or hives

The following side effects have been reported, however the precise frequency cannot be identified and therefore how often they occur is classed as 'not known':

- Unexpected production of breast milk in some women
- Redness or itching of the skin
- Increase in certain liver enzymes
- Problems walking

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:

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SIBELIUM

Keep out of the sight and reach of children.

Sibelium Tablets should not be stored above 25°C (77°F).

Do not take Sibelium Tablets after the expiry date, which is printed on the blister packaging and carton after the letters EXP. 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 SIBELIUM contains

- **The active substance is** flunarizine. Each tablet contains 5mg of flunarizine as flunarizine dihydrochloride.
- **The other ingredients are** lactose monohydrate, maize starch, magnesium stearate, colloidal anhydrous silica, hypromellose, polysorbate 20, microcrystalline cellulose and croscarmellose sodium. See section 2, 'Sibelium Tablets contain lactose' for further information.

What SIBELIUM looks like and contents of the pack

Each tablet is white, oblong shape and inscribed 'J-C' on one side and 'FL 5' on the other side. The tablets are supplied in blister packs in a carton containing 20 tablets.

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