

Package leaflet: Information for the user

Slozem[®]**SLOZEM 120MG, 180MG, 240MG, 300MG CAPSULES***(Diltiazem Hydrochloride)*

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, pharmacist or nurse.
- 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.

What is in this leaflet:

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

1. What Slozem is and what it is used for

Slozem is a capsule containing 120mg, 180mg, 240mg or 300mg of the active ingredient diltiazem hydrochloride. It is used in the treatment of blood pressure that is higher than normal and for the treatment of angina. Angina is a heart condition that results in pain and tightness across the chest and is caused by a narrowing of the blood vessels within the heart itself. When these blood vessels narrow the heart muscles do not get enough oxygen and this causes pain. This pain is similar to the pain caused by cramp in the legs and happens for similar reasons. The diltiazem hydrochloride in Slozem works by dilating blood vessels i.e. making them wider. This has the effect of lowering the blood pressure. This widening of blood vessels in the heart also allows blood to flow better in the heart's blood vessels and eases the pain of angina.

2. What you need to know before you take Slozem**Do not take Slozem**

- if you are hypersensitive (allergic) to diltiazem or any of the other ingredients of Slozem. (The other ingredients are detailed in section 6, "Contents of the pack and other information")
- if you have heart failure that is not being treated or have a heart condition such as: bradycardia (a slower than normal heart beat), sick sinus syndrome (a condition which causes an irregular heartbeat), second or third degree AV block (a condition which affects the way in which the heart beats)
- if you are undergoing an infusion of dantrolene (a muscle relaxant)
- if you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Slozem.

As Slozem is used to treat heart conditions, your doctor may carry out or arrange additional tests to monitor your heart condition during your treatment. This could include an ECG test.

Your doctor will closely monitor how you respond to your treatment if:

- you have reduced left ventricular function. This is a condition which affects how well the heart pumps out blood to the body.
- you have bradycardia (a slower than normal heart beat).
- any previous ECG testing shows any unusual features.
- you have first degree heart block (a condition in which nerve signals to the heart are disturbed, causing it to beat irregularly).
- you are elderly or you have kidney or liver problems.

If you are due to have an operation that requires an anaesthetic make sure that the surgeon knows you are taking Slozem.

Slozem can cause changes in mood, including depression.

Slozem can also inhibit bowel movements, so tell your doctor if you know that you are at risk of developing a bowel obstruction (for example if you suffer from severe constipation).

You may notice remains of the capsules in your stools, but this is nothing to worry about.

Other medicines and Slozem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines can sometimes interfere with each other. They can affect how each medicine is used by the body and can change how quickly each of them works, or how much time each of them stays in the body. This may increase the unwanted effects or side effects of the different medicines, and sometimes the medicine will not work properly.

Your doctor may limit your use of diltiazem or other medicines, or you may need to take a different medicine. It is especially important to mention if you are taking the following medicines:

- Dantrolene infusion - a muscle relaxant. Slozem must not be taken with dantrolene.
- Lithium - used to treat depression.
- Nitrates, such as glyceryl trinitrate (GTN), used to treat angina.
- Theophylline, used to treat breathing difficulties such as asthma.
- Alpha blockers such as prazosin, which are used to treat high blood pressure.
- Digoxin, used for heart conditions and heart failure.
- Other medicines to treat high blood pressure or to treat a heart condition such as beta blockers (e.g. propranolol) or antiarrhythmic medicines (e.g. amiodarone).
- Carbamazepine, which is used in the treatment of epilepsy and bipolar disorder (a psychiatric condition).
- Rifampicin - an antibiotic.
- Medicines used to treat heartburn or stomach ulcers such as cimetidine or ranitidine, as these can increase blood levels of diltiazem.
- Ciclosporin, tacrolimus and sirolimus which may be used following organ transplants to help prevent rejection.
- Benzodiazepines (tranquilisers) such as midazolam and triazolam.
- Corticosteroids such as methylprednisolone
- Statins such as simvastatin which are used to lower levels of cholesterol in the body
- Diuretics ("water tablets") such as frusemide or spironolactone.
- ACE inhibitors such as lisinopril or captopril.
- Tricyclic antidepressants such as imipramine and amitriptyline.
- Erythromycin which is used to treat infections.

Slozem with food and drink

There are no specific foods that need to be avoided.

Pregnancy and breast-feeding**Pregnancy**

Do not take Slozem if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

Breast-feeding

Do not take Slozem if you are breast-feeding, as it can reach your baby through your breast milk.

Driving and using machines

Slozem may make you feel dizzy or unwell. Do not drive or operate machinery until you know how it will affect you.

Slozem contains Sucrose

As Slozem contains sucrose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Slozem.

The full ingredient list is in section 6 "Contents of the pack and other information".

3. How to take Slozem

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Capsules should be swallowed with a glass of water.

When you first start taking Slozem the usual dose will be 240mg of diltiazem per day.

If your doctor prescribes a different daily dose make sure you know how many capsules you need to take. If you are not sure, it is very important that you ask your doctor or a pharmacist for advice.

Your doctor should monitor you, and may change your dose depending on how well Slozem works for you. If needed, you may be given a different strength of Slozem capsules.

If you are elderly or have liver or kidney problems, you will usually be prescribed a lower starting dose of 120mg of Slozem per day.

Use in children

Slozem is not recommended for use in children.

If you take more Slozem than you should

Contact your doctor or nearest hospital for advice as soon as you realise you have taken too many capsules as symptoms of overdose may take some time to appear. Take the container and any remaining capsules with you. Overdose causes low blood pressure, slow heart beat, or abnormal blood sugar levels. It could also cause your heart to stop beating. Initial symptoms include tiredness, confusion, and forgetfulness. The low blood pressure can cause swollen ankles.



If you forget to take Slozem

If you miss taking your capsule at the normal time, take it as soon as possible if it is less than 12 hours after the usual time of taking your capsule. If you are more than 12 hours late, then wait and take your next capsule at the usual time on the following day. Do not take a double dose to make up for the missed dose.

If you stop taking Slozem

Talk to your doctor before you stop taking Slozem.

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

4. Possible side effects

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

Serious side effects

- Heart conditions including sino-atrial block, atrio-ventricular block or congestive heart failure which cause changes in the way the heart beats. This can cause dizziness, weakness, shortness of breath, confusion, and make exercise more difficult.
- Certain skin reactions including exanthematous pustulosis (numerous small pus filled spots over the body with fever) and erythema multiforme (red spots - sometimes with purple or blistered areas in the centre - which appear on the skin, mouth, eyes and other moist surfaces)
- Hepatitis - inflammation of the liver. Symptoms include yellowing of the skin and whites of the eyes. In the few cases that have happened, hepatitis resolved completely once the patient stopped taking Slozem.
- Drug-induced Parkinsonism which causes uncontrollable shaking and difficulty in moving normally.

Contact your doctor immediately if you notice any of the above symptoms.

Other side effects

Other side effects tend to be less serious in nature.

Side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

Very Common:

- swollen ankles - this side effect depends on the dose used and tends to happen more often in elderly patients.

Common:

- general tiredness and feeling unwell
- headache
- dizziness
- hot flushes
- redness of the skin
- feeling sick
- loss of appetite
- stomach upset
- constipation
- palpitations

Uncommon:

- nervousness
- sleeping difficulties
- slow heart rate
- low blood pressure on standing up which causes dizziness, weakness and confusion
- vomiting
- diarrhoea
- blood tests showing changes in the liver - typically during the beginning of treatment

Rare:

- dry mouth
- raised itchy areas of skin

Unknown frequency:

- a decrease in the number of cells called "platelets" in the blood. This may cause bleeding or a tendency to bruise easily.
- inflammation of blood vessels causing local swelling and redness
- mood changes including depression
- involuntary muscle movements or spasms that usually occur in the face and neck
- swollen gums
- increase in the sensitivity of the skin to sunlight
- skin rashes
- sweating
- swellings under the skin
- gynaecomastia (breast enlargement in men)

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 Slozem

The 120mg, 180mg and 240mg capsules should not be stored above 30°C.

The 300mg capsules should not be stored above 25°C.

Slozem should be kept in the original container supplied to you by your pharmacist.

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

Do not use this medicine after the expiry date which is stated on the carton after '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 Slozem contains

The active substance is diltiazem hydrochloride.

The other ingredients are: maize starch, sucrose, povidone, shellac, ethylcellulose, and talc.

The capsules* are made with gelatine. Erythrosine (E127) and indigo carmine (E132) are used to colour the capsules. For the 180mg, 240mg and 300mg capsules titanium dioxide (E171) is also used to colour the capsules.

The printing ink used to mark the capsules contains black iron oxide (E172), shellac, and propylene glycol.

What Slozem looks like and contents of the pack

Slozem is presented as packs of 28 capsules in PVC/PVDC/Aluminium blisters enclosed in a cardboard carton.

Slozem capsules are pink and white in colour (120mg and 180mg capsules) or red and white in colour (240mg and 300mg capsules).

*DIFFUCAPS - Trademark of Adare Pharmaceuticals S.r.l

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