Package leaflet: Information for the user

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 or 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 or 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 belongs to a group of medicines called calcium channel blockers and 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 allergic (hypersensitive) to diltiazem or any of the other ingredients of Slozem (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 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.
- if you are breast-feeding or planning to breast feed (see the section below 'Pregnancy and breast-feeding')
- if you are already taking a medicine containing lomitapide used for treatment of high cholesterol levels (see the section: 'Other medicines and Slozem').
- if you are already taking a medicine containing **asunaprevir** used for the treatment of hepatitis C virus infection (see section below: 'Other medicines and Slozem').

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 Slozem.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Slozem if you:
- have a history of heart failure, new shortness of breath, slow breath or low blood pressure. As cases of kidney injury in patient with such conditions have been reported, your doctor may need to monitor your kidney function.
- have any other problem with your heart, apart from angina or those described in the previous section
- are going to have an operation
- are at risk of mood changes, including depression
- are at risk of gut problems.

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).

Your doctor will check you more closely when starting to take Slozem if you:
- are over 65 years of age
- have kidney or liver problems.
- have diabetes
- have ever had asthma
- take any beta blocker medicines.

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.

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

Other medicines and Slozem
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Slozem can affect the way some other medicines work. Also, some medicines can affect the way Slozem work.

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.
- Medicines containing ivabradine used for the treatment of certain heart diseases.
- Medicines containing lomitapide used for the treatment of high cholesterol levels. Diltiazem may increase the concentration of the lomitapide that may lead to an increase in the likelihood and severity of liver related side effects.
- Medicines containing **asunaprevir** used for the treatment of hepatitis C virus infection. Diltiazem may increase the concentration of the asunaprevir that may lead to an increase in the likelihood and severity of liver related side effects.
- Phenytoin used for epilepsy
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel
- Oral anticoagulants such as apixaban, rivaroxaban, dabigatran, or edoxaban.
- Iodinated contrast media (used for tests involving x-rays)
- Cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.
- Rifampicin used to treat tuberculosis (TB)
- Medicines that lengthen your heart beat (the QT interval) such as medicines for infection (such as clarithromycin, ciprofloxacin, ofloxacin or levofloxacin).
- Colchicine- used to treat gout.

Slozem with food and drink
It is advisable to limit the amount of grapefruit juice you drink while taking Slozem as it can increase the blood levels of the active ingredient diltiazem, and may increase your chance of getting side effects.
If you are concerned, you should stop drinking grapefruit juice and consult your doctor.

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. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

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
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Slozem.

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
If you take more capsules 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 doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, slurred speech, confusion, decrease of kidney function, coma, and sudden death. Overdose causes low blood pressure, slow heartbeat, 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.
Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

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.

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

Not known (frequency cannot be estimated from the available data):
- You have an allergic reaction. The signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a red or lumpy skin rash, swollen eyelids, face, lips, throat, or tongue, difficulty in swallowing.
- Your asthma gets worse.
- You have difficulty breathing, wheezing, tightness in the chest (called bronchospasm).
- You get blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be an illness called Stevens-Johnson syndrome.
- You get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body.
- An itchy, purple, raised rash.
- You may feel generally unwell and have a fever, chills and aching muscles. This could be an illness called Toxic Epidermal Necrolysis.
- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called erythema multiforme.
- A condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes (called 'lupus-like syndrome').

Tell your doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:
- 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
- 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.
- Drug-induced Parkinsonism which causes uncontrollable shaking and difficulty in moving normally.

Other side effects

Very common (may affect more than 1 in 10 people)
- swollen ankles, this side effect depends on the dose used and tends to happen more often in elderly patients.

Common (may affect up to 1 in 100 people)
- general tiredness and feeling unwell
- headache
- dizziness
- hot flushes
- redness of the skin
- feeling sick
- loss of appetite
- stomach upset
- constipation
- palpitations

Uncommon (may affect up to 1 in 1,000 people)
- 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 (may affect up to 1 in 10,000 people)
- dry mouth
- raised itchy areas of skin

Not Known (frequency cannot be estimated from the available data)
- 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 side effects
If you get any side effects, talk to your doctor or 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 Pharmaceutical S.r.l

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