Package leaflet: Information for the patient

Sormon 60 mg Prolonged-release Tablets
(isosorbide mononitrate)

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

What is in this leaflet

1. What Sormon is and what it is used for

Sormon contains isosorbide mononitrate which belongs to a family of medicines known as nitrates. These medicines allow the blood vessels around the heart to relax and widen, allowing more blood to flow to the heart and around the body. Your medicine is in the form of a 'prolonged-release' tablet, which slowly releases the medicine into your body.

Sormon can be used to help prevent angina (a muscle cramp of the heart). However, Sormon is **not** a suitable treatment for the relief of acute angina. If you suffer from an acute attack of angina, a more suitable medicine should be taken. Do not stop taking Sormon without first consulting your doctor or pharmacist.

2. What you need to know before you take Sormon

Do not take Sormon:
- if you are allergic to isosorbide mononitrate, other nitrates, or any of the other ingredients of this medicine (listed in section 6).
- if you have heart conditions such as swelling of the lining that surrounds the heart, problems with your heart muscle or valves.
- if you are taking sildenafil or similar medicines called "phosphodiesterase type-5 inhibitors" normally used to treat male impotence (erectile dysfunction).
- if you have very low blood pressure or problems with blood flow to the brain which may be due to blood pressure or blood vessel problems e.g. a stroke or a brain injury.
- if you have a condition called "cardiogenic shock" which may occur after a heart attack when the body cannot pump enough blood around the body.

Warnings and precautions
Talk to your doctor or pharmacist before taking Sormon

- if you have severe anaemia
- if you have hypothyroidism (underactive thyroid)
- if you have raised pressure in the head (intra-cranial pressure)
- if you have severe liver or kidney problems
- if you are malnourished or are unable to regulate body temperature (hypothermia) or develop these during treatment.
- if you have hypoxaemia (low oxygen level in your blood, due to lung disease for example).

Other medicines and Sormon
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. Do not take Sormon with sildenafil or other phosphodiesterase type-5 inhibitors normally used to treat male impotence. If you take one of these medicines for erectile dysfunction, taking Sormon as well can cause a severe and possibly dangerous fall in blood pressure. This could result in fainting, or even a heart attack.

If you are taking any of the following medicines it is important you talk to your doctor or pharmacist.

- medicines for heart problems such as beta-blockers e.g. sotalol, carvedilol
- diuretics, used to increase urination e.g. furosemide, hydrochlorothiazide
- medicines for depression (called tricyclic antidepressants) e.g. mirtazapine, trimipramine
- medicines used to treat anxiety and mental health conditions e.g. tranquillisers
- alprostadil (a prostaglandin), another drug used for the treatment of male impotence
- dihydroergotamine (used to treat migraines)
- medicines that lower the blood pressure as their effect may become more pronounced (including vasodilators, antihypertensives, calcium channel blockers and angiotensin II receptor antagonists)
- aldesleukin, a medicine used for the treatment of cancer

Sormon with alcohol
Alcohol may increase the effect of reducing your blood pressure and may also make you drowsy. The use of alcohol should therefore be avoided.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or operate machines if you feel dizzy or weak.

Sormon contains lactose
If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicine.

3. How to take Sormon

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

The recommended starting dose is half a tablet (30 mg) a day for the first two to four days.

The tablet can be divided into equal doses.

After this, the recommended dose is one tablet (60 mg) a day, taken in the morning. When necessary, the dose may be increased to two tablets (120 mg) a day, taken together in the morning.

Swallow the tablets with half a glass of water, in the morning.
Do not crush or chew the tablets, although you can divide them into equal doses if required.

During treatment
When you are taking this medicine, you may notice the remains of the tablet in your faeces. This is not a sign that this medicine is less effective. The medicine is released from the tablet leaving behind part of the tablet which you may pass in faeces.

Use in children and adolescents
Do not give these tablets to children and adolescents.

If you take more Sormon than you should
The signs of an overdose may include headache, tiredness, flushing, feeling sick (nausea), vomiting, fast heart rate, diarrhoea, 'spinning' sensation or dizziness and fainting which may be due to low blood pressure. Large amounts of this medicine may cause a 'blueing' of the skin e.g. lips, or changes to breathing e.g. shortness of breath or slower breathing. If you suddenly experience any of the above, lie down with your legs raised slightly as this may help to ease the symptoms.

Contact your doctor or pharmacist immediately or go to the accident and emergency department of your local hospital at once. Take the carton or container of medicine with you, even if it is empty.

If you forget to take Sormon
Do not take a double dose to make up for a forgotten dose. If it is almost time for your next dose, simply carry on as before.

If you stop taking Sormon
Do not stop taking these tablets without consulting your doctor or pharmacist as your chest pains may re-occur or get worse.

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.

Side effects due to Sormon are more likely to occur at the start of treatment.

If you experience any of the following, seek immediate medical attention:
- signs of very low blood pressure such as:
    - pale, cold, clammy or blueish skin,
    - rapid, shallow breathing,
    - fast heart rate with dizziness,
    - a weak pulse,
    - confusion, anxiety or loss of consciousness

  These may be signs of circulatory collapse, a condition that can lead to an insufficient supply of oxygen to the brain, kidneys, skin, and other parts of the body. (Not known)

Other side effects

Very common (may affect more than 1 in 10 people)
- headache

Common (may affect up to 1 in 10 people)

- dizziness
- feeling tired
- low blood pressure
- fast heart beat
- feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people)
- flushing
- vomiting
- diarrhoea

Rare (may affect up to 1 in 1,000 people)
- fainting
- skin rash or itching

Very rare (may affect up to 1 in 10,000 people)
- aching muscles, muscle tenderness or weakness, not caused by exercise (myalgia)

Not known (frequency cannot be estimated from the available data)
- feeling sleepy
- worsening of angina pectoris
- slow heartbeat
- low blood pressure causing dizziness when standing up
- flaking or scaly skin, blisters
- allergic skin reactions that may include bumps, redness and itching on your skin

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Sormon

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicine 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 Sormon contains
Each tablet contains 60 mg of Isosorbide mononitrate.
The other ingredients are cellulose microcrystalline, kaolin heavy, magnesium stearate, silica colloidal anhydrous, synthetic paraffin wax and hard paraffin wax. The coating contains hypromellose, titanium dioxide (E171), lactose monohydrate (see section 2 "Sormon contains lactose"), macrogol, iron oxide yellow (E172), iron oxide black (E172) and iron oxide red (E172).

What Sormon looks like and contents of the pack
Sormon are pale yellow, elliptical, film-coated tablets, marked with 'IM' breakline '60' on one side and a break line on the reverse.

Sormon are available in plastic containers with an optional plastic spacer at the top of the pack and blister packs of 7, 14, 28, 30, 60, 90, 98, 100, 100x1, 250 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Viatris Limited
Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

Manufacturer
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Mylan Hungary Kft., Mylan utca1, Komarom 2900, Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:
Denmark – Fem-Mono Retard, depottabletter 60 mg
Iceland – Fem-Mono Retard
Ireland – Sormon 60 mg prolonged-release tablets
Netherlands – Isosorbide Mononitraat Retard Viatris 60 mg, tabletten met gereguleerde afgifte
Portugal – Mononitrato de Isossorbido Mylan 60 mg comprimidos de liberacao prolongada
United Kingdom – Monigen XL 60 mg prolonged release tablets

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