

INFORMATION FOR THE CONSUMER

IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT PRO-ISMN

Read this leaflet carefully. It has been prepared by the makers of PRO-ISMN to help you get the most benefit from this drug. It contains general points about PRO-ISMN and should add to more specific advice from your doctor or pharmacist.

This leaflet should not replace your doctor's or pharmacist's advice. Because of your health condition, they may have given you additional instructions. If so, be sure to follow their advice. Also, if you have any questions or concerns after reading this leaflet, talk to your doctor or pharmacist. **Do not decide on your own to stop taking PRO-ISMN.**

WHAT IS PRO-ISMN?

PRO-ISMN is the name for the extended release formulation of isosorbide-5-mononitrate, which is released gradually over a 10-hour period. PRO-ISMN belongs to a family of drugs called nitrates that function by dilating blood vessels.

PRO-ISMN is used to prevent severe chest pain and feeling of pressure around the heart (recurring angina pectoris). PRO-ISMN is not intended for the immediate relief of sharp chest pains (acute angina pectoris).

WHAT SHOULD I TELL MY DOCTOR BEFORE STARTING PRO-ISMN?

Be sure you've told your doctor:

- about all health problems you have now, and have had in the past;
- about all other medicines you take, including any you take for high blood pressure, and ones you can buy without a prescription;
- if you are pregnant, plan to become pregnant, or are breast feeding;
- if you have ever had an allergic, bad or unusual reaction to nitrates or to any medicine for heart problems;
- if you are allergic to non-medicinal substances like food products, preservatives, or dyes, which may be present in PRO-ISMN (see What Does PRO-ISMN Contain?).

WHAT DOES PRO-ISMN CONTAIN?

Most medicines contain more than their "active" ingredient. These other ingredients are needed to keep medicines in a form you can use. For people with certain allergies, the following is a list of all ingredients in PRO-ISMN. Check with your doctor if you think you might be sensitive to any of these items.

The active ingredient in PRO-ISMN is isosorbide-5-mononitrate. Non-medicinal ingredients are: colloidal silicon dioxide, hydroxypropylmethylcellulose, stearic acid and yellow ferric oxide.

HOW DO I TAKE PRO-ISMN?

Take PRO-ISMN exactly as your doctor tells you. Usually, this is one tablet in the morning. If your doctor tells you to take two tablets each day, they must be taken together in the morning. Check with your doctor or pharmacist if you have any questions about your directions.

PRO-ISMN tablets should be swallowed whole, with half a glass of water or other liquid e.g., fruit juice or milk. **Do not chew or crush the tablets.**

If needed, the tablets may be broken in half along the scored line.

Do not take extra doses of PRO-ISMN, unless your doctor tells you. Using more can increase the chance of unwanted effects.

WHAT DO I DO IF I MISS A DOSE?

It is important to take PRO-ISMN at about the same time every day.

If you miss a dose of PRO-ISMN and remember within 6 hours, take your usual dose as soon as possible. Then go back to your regular schedule. But if it is more than 6 hours when you remember, do not take the missed dose. Just take the next dose on time.

Never take a double dose of PRO-ISMN to make up for missed tablets. If you are still unsure, check with your doctor or pharmacist to see what you should do.

WHAT ARE THE SIDE EFFECTS OF PRO-ISMN?

PRO-ISMN, like any medication, may produce side effects.

The most common side effect is headache. It often occurs at the beginning of the treatment, but usually goes away after a few days. If you get a bad headache, and it becomes a problem, be sure to tell your doctor.

If too much PRO-ISMN is taken, a severe pulsing headache might occur. You may feel lightheaded, dizzy, excited, flushed, have cold sweats, nausea (feeling sick) and vomiting. If any of these symptoms occur, lie down with your feet raised and get someone to call your doctor right away.

Some people feel PRO-ISMN makes them dizzy, faint, or tired. This is more likely when PRO-ISMN is first started. If you have any of these effects, please tell your doctor.

Do not stop taking PRO-ISMN until your doctor tells you. He or she may want to reduce your dose slowly.

Remember, medicines affect different people in different ways. Just because other people have had side effects does not mean you will get them. Discuss how you feel on PRO-ISMN with your doctor or pharmacist.

Other side effects which cannot be predicted may occur in rare cases. If you have any bothersome or unusual effects while using PRO-ISMN, check with your doctor or pharmacist right away.

ARE THERE ANY SPECIAL PRECAUTIONS?

If you are taking PRO-ISMN, you must not take phosphodiesterase type 5 inhibitors (i.e. Viagra® (sildenafil), Cialis® (tadalafil), Levitra® (vardenafil)). Such a combination can produce severe lowering of blood pressure, loss of consciousness, heart attack, or death.

Unused medicines which you know you will no longer need should be carefully discarded. Small quantities may be disposed of in the toilet or you may wish to seek advice from your pharmacist.

HOW DO I STORE PRO-ISMN?

Although PRO-ISMN tablets are protected in the bottle, it is best to keep it at normal room temperature and in a dry place. Do not keep PRO-ISMN in the bathroom. Do not keep or use PRO-ISMN after the expiry date marked on the bottle.

Do not transfer PRO-ISMN to other containers. To protect your PRO-ISMN tablets, keep them in the original bottle.

Keep PRO-ISMN out of the reach of children. Never take medicine in front of small children as they may want to copy you.

GENERAL INFORMATION

PRO-ISMN is for your current condition only. Do not use it for other problems unless your doctor tells you. Never give it to other people to use.

Be sure to tell your doctors, dentists and pharmacists that you take PRO-ISMN.

All drugs can have both helpful and harmful effects. Both depend on the person and his or her health condition. This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor with any questions or concerns you have about PRO-ISMN.

For more information, please contact your pharmacist, doctor or other healthcare professional or Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
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REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to : Canada Vigilance Program
Health Canada
Postal Locator: 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.