

Drug Information Sheet("Kusuri-no-Shiori")

External

Revised: 11/2014

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Myocor spray 0.3mg

Active ingredient: Nitroglycerin

Dosage form: metered-dose sublingual spray, diameter 22 mm, height approx. 78mm

Print on wrapping:



Effects of this medicine

This medicine has vasodilatory effects on coronary arteries to increase blood flow. These effects improve the transport of both oxygen and nutrition into cardiac cells and reduce systemic vascular resistance, arterial pressure and workload in the heart.

This medicine is to be used for the acute relief of angina attacks.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines.
- If you have hypotension, angle-closure glaucoma, head trauma, cerebral hemorrhage, or anemia.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is << to be written by a healthcare professional >>
- In general, for adults, one spray (containing 0.3 mg of nitroglycerin) should be administered under the tongue. If there is no improvement in symptoms after about 3 minutes, at most one additional spray is allowed. Strictly follow the instructions.
- At the onset of an attack, if possible before using the spray, find somewhere to sit down, hold the container vertically close to your mouth and then spray toward the sublingual region (underside of the tongue) while holding your breath.
- Before this product is used for the first time, the pump must be sprayed into the air 6 or 7 times while the container is held upright (This is known as priming). When priming the container, actuate the spray into the air away from yourself and others. If the spray has not been used for more than one month, or if the container has been stored or carried either horizontally or upside down, before use, confirm whether a sufficient amount of drug solution is released after priming.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Alcohol may enhance the vasodilatory effect and cause hypotension.
- Headache, as a side effect, may impair your attentiveness, concentration and/or reflexes. If you feel these symptoms, avoid operating a motor vehicle or machinery.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, tongue numbness/irritation/pain and rash. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

No pertinent entries.

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep this medicine out of the reach of infants and children. Store away from direct sunlight, heat (40 degrees Celsius (104 degrees Fahrenheit) or more) and fire.
- Keep or carry this medicine preferably upright in a location where you can use it immediately.
- Medicine that has been used more than the number of spray applications shown on the container label or which is

beyond its expiration period must be discarded. DO NOT keep it. To dispose of this medicine, follow the appropriate method described in the attached information for patients.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.