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

Internal

Revised: 05/2021

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: Nitropen Tab. 0.3mg

Active ingredient: Nitroglycerin

**Dosage form:** white tablet, diameter: 5.0 mm, thickness: 2.4 mm

Imprint or print on wrapping:(front)ニトロペン舌下錠 0.3mg, Nitropen Tab.0.3mg,

NK2015,ここに錠剤は入っておりません (back) ニトロペン舌下錠 0.3mg

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### Effects of this medicine

This medicine supplies blood and oxygen to the heart followed by dilating coronary artery. It also decreases systemic venous vascular resistance and reduces the workload of the heart.

It is usually used to relieve an attack of angina, myocardial infarction and cardiac asthma, and to pass food easily by relaxing the muscle of the narrowed esophagus.

# The following patients may need to be careful when 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 or foods. If you have: hypotension, angle-closure glaucoma, head injury, intracranial hemorrhage, anemia, primary pulmonary hypertension or obstructive hypertrophic cardiomyopathy.
- · 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, place 1 to 2 tablets (0.3 to 0.6 mg of the active ingredient) under the tongue at a time to dissolve the tablets with saliva. In angina pectoris, if the medication does not show effect within a few minutes, you may take an additional 1 to 2 tablets (0.3 to 0.6 mg of the active ingredient). The dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.
- •Do not swallow the tablets. If you have difficulty dissolving a tablet due to dry mouth, moisten the tongue with water or chew the tablet and place under the tongue.
- •For angina pectoris: The medication shows effect within a few minutes, in general. If it does not show effect, an additional 1 to 2 tablets (0.3 to 0.6 mg of the active ingredient) under the tongue. If the symptom is not improved after you take up to 3 tablets during an episode of angina pectoris, if the attack lasts 15 to 20 minutes or longer, contact your doctor immediately.
- •When you use this medicine, sometimes the blood pressure falls too low and it may cause dizziness. Do not leave standing when you take it, please sit down and take.
- •When you take the medicine for the first time, be sure to take only 1 tablet for the first few times. Transient headache may occur after taking this medicine. It will diminish while you are continuing taking this medicine.
- •For angina pectoris: If the symptom is not improved after you take up to 3 tablets during an episode of angina pectoris, if the attack lasts 15 to 20 minutes or longer, contact your doctor immediately or go to an emergency hospital right away.
- ·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

- This medicine may cause decline of attention, concentration and reflex movement due to headache and dizziness etc. Avoid operating dangerous machinery such as driving a car.
- •Alcohol may intensify the vasodilatory effect of the medicine and cause hypotension. Be careful when you drink alcohol.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include cerebral anemia, falling blood pressure, feverish, hot flush, palpitation, headache, nausea and vomiting. 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 out of reach of children. Store away from direct sunlight, heat and moisture.
- The medicine should be carried and kept in the aluminum bag to protect tablet from damage. Do not transfer the medicine from the aluminum bag to other containers. If the aluminum bag breaks or gets wrinkled, take new one. Do not put the medicine in your hip pocket since the tablets may be crushed.
- •Discard the remainder. Do not store them. Ask the pharmacist or medical institution how to discard them.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.