

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

Internal

Revised: 07/2015

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: DORNER Tablets 20mcg

Active ingredient: Beraprost sodium

Dosage form: white to pale yellowish white tablet (diameter: 6.2mm, thickness: 2.8mm)

Print on wrapping: (Face) ドルナー20 μ g, TR212, house-mark, (Back) ドルナー20 μ g, house-mark



Effects of this medicine

This medicine increases the blood flow by exerting potent effects on prostacyclin receptors on blood vessel and platelets, thus vasodilating and inhibiting blood clotting.

It is usually used for the treatment of pain, cold feeling and skin sores of the hands and feet due to chronic arterial occlusion, as well as for the treatment of primary pulmonary hypertension.

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 bleeding due to haemophilia, capillary fragility, upper gastrointestinal ulcer, urinary tract haemorrhage, haemoptysis, bleeding of the ocular fundus, etc.
- If you are pregnant, possibly 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 >>
- For the improvement of ulcer, pain and cold feeling due to chronic arterial occlusion: In general, for adults, take 2 tablets (40 mcg of the active ingredient) at a time, 3 times daily after meals.
For the treatment of primary pulmonary hypertension: In general, for adults, take 1 tablet (20 mcg of the active ingredient) at a time, 3 times daily after meals. The dosage may be increased gradually according to your symptoms. If the dose is increased, it may be taken 3 to 4 times daily, and the maximum daily dose should not exceed 9 tablets (180 mcg).
In any case, strictly follow the instructions.
- If you miss a dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- 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

- Since this medicine may cause disturbance of consciousness etc., pay close attention when you operate dangerous machinery such as driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, flushed face, hot flush, diarrhoea, queasy, malaise, bleeding tendency, subcutaneous haemorrhage, epistaxis, anaemia, rash, eczema, itching, urticaria and erythema. 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.

- headache, queasy, visual impairment [cerebral haemorrhage, haemorrhage of the digestive tract, pulmonary haemorrhage, bleeding of the ocular fundus]
- facial pallor, cold sweat, dizziness on standing up, loss of consciousness [shock, syncope, loss of consciousness]
- fever, dry cough, breathing difficulty [interstitial pneumonia]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eye [hepatic function disorder]
- chest pressure sensation, chest pain with strangled feeling, cold sweat [angina pectoris, myocardial infarction]

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 the reach of infants and children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical facility when you

discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.