

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

Internal

Revised: 09/2024

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:**BERAPROST Na TABLETS 20mcg 「OHARA」

**Active ingredient:**Beraprost sodium

**Dosage form:**white to pale yellowish white tablet, diameter: 6.1 mm, thickness: 2.7 mm

**Imprint or print on wrapping:**ベラプロスト Na20  $\mu$ g「オーハラ」, 20  $\mu$ g, Beraprost Na 20  $\mu$ g「OHARA」



## **Effects of this medicine**

This medicine binds to prostaglandin I<sub>2</sub> receptor in platelets and vascular smooth muscle to prevent blood coagulation. It consequently dilates blood vessels and improves blood flow.

It is usually used to improve ulcer, pain and coldness associated with chronic arterial obstruction. It is also used for essential pulmonary hypertension.

## **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 are bleeding (hemophilia, capillary fragility, upper gastrointestinal bleeding, urinary tract bleeding, hemoptysis, fundus bleeding, 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 improvement of ulcer, pain and coldness associated with chronic arterial obstruction: In general, for adults, take 2 tablets (40 mcg of the active ingredient) at a time, 3 times a day after meals.
- For essential pulmonary hypertension: In general, for adults, take 1 tablet (20 mcg of the active ingredient) at a time, 3 times a day after meals. The dosage will be gradually increased according to your symptoms. If the dose is increased, it may be taken 3 to 4 times a day, and the maximum daily dose is 9 tablets (180 mcg) in 3 to 4 divided doses.
- Strictly follow the instructions in any case.
- If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next 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**

- You should be well informed that close attention to performing dangerous operations such as driving a car is needed, since conscious disorder may occur.

## **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include headache, facial flush, hot flush, nausea, diarrhea, bleeding tendency, subcutaneous bleeding, nose bleeding, anemia, rash, eczema, itch, hives 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, vomiting of blood/melena, reduced visual acuity [bleeding tendency, gastrointestinal bleeding, pulmonary bleeding, fundus bleeding]
- dizziness, facial pallor, nausea [shock, syncope, loss of consciousness]
- fever, dry cough, respiratory distress [interstitial pneumonia]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]
- tightness in the chest, feeling of tightness, cold sweat [angina, 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 children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or

medical institution. Do not give the unused medicines to others.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

SIE③