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

Internal

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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: EPALRESTAT TABLETS 50mg [OHARA]

**Active ingredient:**Epalrestat

**Dosage form:**white tablet, diameter: 6.7 mm, thickness: 4.0 mm

**Print on wrapping:**エパルレスタット 50mg「オーハラ」, 50mg, 食前に服用,

Epalrestat50mg「OHARA」



#### Effects of this medicine

This medicine suppresses accumulation of sorbitol in cells by inhibiting action of aldose reductase which converts glucose of sugar to sorbitol. It consequently improves peripheral neuropathy due to sorbitol accumulation. It is usually used to improve numbness, pain and abnormality of vibration sensation/heart rate variability associated with diabetic peripheral neuropathy.

#### 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 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<</li>
- to be written by a healthcare professional>>
- •In general, for adults, take 1 tablet (50 mg of the active ingredient) at a time, 3 times a day before meals. The dosage may be adjusted according to your age and symptoms. Strictly follow the instructions.
- 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

•Your urinary color may turn yellowish brown or red due to color of the component of this medicine. Do not worry about the change.

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include abdominal pain, nausea, dull, rash, itch, erythema and blister. 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.

- •general malaise, loss of appetite, yellowing of the skin and the white of eyes [fulminant hepatitis, liver dysfunction, jaundice, liver failure]
- •nasal bleeding, gum bleeding, subcutaneous bleeding of limbs [thrombocytopenia]

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.
- ${}^{\textstyle \bullet} \textsc{Discard}$  the remainder. Do not store them.

# For healthcare professional use only

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For further information, talk to your doctor or pharmacist.

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