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

Internal

Revised: 05/2019
v authority. Approval

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: Takepron OD Tablets 15 [agents for digestive organ]

Active ingredient:Lansoprazole

Dosage form: white to yellowish white tablets with flecks of red-brown to dark-brown,

diameter: 8.5 mm, thickness: 4.6 mm

Imprint or print on wrapping:(Face) 212 15 (Back) タケプロン OD15

Effects of this medicine

This medicine inhibits gastric acid secretion by inhibiting enzyme activity of the proton pump in the gastric mucosa. It is usually used for treatment of gastric/duodenal ulcer, reflux esophagitis, non-erosive gastroesophageal reflux disease, etc., and for suppression of recurrence of gastric/duodenal ulcer associated with low-dose aspirin or nonsteroidal anti-inflammatory drug medication.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- · If you ever experienced any allergic reaction (itch, rash etc.) to any medicines or foods.
- If you have liver disorder.
- · 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))
- For treatment of gastric/duodenal ulcer, reflux esophagitis, etc.: In general, for adults, take 2 tablets (30 mg of the active ingredient) at a time, once a day.

For maintenance therapy of repeatedly recurrent/relapsing reflux esophagitis: In general, for adults, take 1 tablet (15 mg of the active ingredient) at a time, once a day. The dosage may be increased up to 2 tablets (30 mg of the active ingredient) at a time, once a day, if the effect is insufficient.

<u>For treatment of non-erosive gastroesophageal reflux disease</u>: In general, for adults, take 1 tablet (15 mg of the active ingredient) at a time, once a day.

For suppression of recurrence of gastric/duodenal ulcer associated with low-dose aspirin or nonsteroidal anti-inflammatory drug medication: In general, for adults, take 1 tablet (15 mg of the active ingredient) at a time, once a day.

Strictly follow the instructions of your doctor/pharmacist in either case.

- This medicine may be moistened with saliva on the tongue, then lightly squashed with the tongue, and swallowed with saliva. It may also be taken with water like usual medicines.
- •If you miss a dose, take the missed dose as soon as possible. However, let more than 8 hours pass before the next dose. DO NOT take double doses to make up for the missed dose.
- ·If you took too much of the medicine (more than prescribed), check with your doctor/pharmacist.
- •Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itching, erythema multiforme, constipation, diarrhea, dry mouth, enlarged feeling of abdomen, nausea, stomach discomfort, headache, sleepiness, fever, and gynecomastia. 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.

- •generalized rash, facial swelling, breathing difficuly [anaphylaxis, shock]
- •dullness, fever, shortness of breath, nose bleeding/subcutaneous hemorrhage, red-brown urine [pancytopenia, agranulocytosis, granulocytopenia, hemolytic anemia, decreased platelet count, anemia]
- •yellowing of the skin and the white of eyes, dullness, loss of appetite [serious liver dysfunction]
- •fever, general malaise, rash or redness of the skin/eyes and in mouth [toxic epidermal necrolysis, mucocutaneous-ocular syndrome]
- •fever, dry cough, breathing difficuly [interstitial pneumonia]
- •fever, rash, joint pain [interstitial nephritis]

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.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.