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

Internal

Published: 06/2021

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: REBAMIPIDE TAB 100mg [EMEC]

Active ingredient: Rebamipide

**Dosage form:**white tablet, diameter: 8.1mm, thickness: 3.4mm

Print on wrapping: (front) レバミピド錠 100mg「EMEC」、レバミピド、100mg,胃炎・胃潰

瘍のお薬

(back) Rebamipide100mg「EMCE」,レバミピド 100mg「EMEC」



#### Effects of this medicine

This medicine suppresses gastric mucosal injuries by increasing effects of gastric mucosal prostaglandin  $E_2$  and protective effect of gastric mucosa. It increases gastric mucus and blood flow in gastric mucosa to improve hemodynamic disorder. It consequently suppresses inflammation and repairs gastric mucosa.

It is usually used in the treatment of gastric ulcer, and for improvement of gastric mucosal lesion (erosion, bleeding, redness and edema) in acute exacerbation period of acute gastritis and chronic gastritis.

### 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(( professional))
- to be written by a healthcare
- For gastric ulcer,: In general, for adults, take 1 tablet (100 mg of the active ingredient) at a time, 3 times a day, in the morning, evening and before going to bed.

For improvement of gastric mucosal lesion (erosion, bleeding, redness and edema) in acute exacerbation period of acute gastritis and chronic gastritis,: In general, for adults, take 1 tablet (100 mg of the active ingredient) at a time, 3 times a day.

Strictly follow the instructions in any case.

- •If you miss a dose, take the missed dose when you remember. 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

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include hypersensitivities such as rash, itch, eczema like drug eruption, and hives. 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.

- •cold sweat, decreased blood pressure, breathing difficulty [shock]
- •swelling around eyes and mouth, hives, breathing difficulty [anaphylactoid symptoms]
- •sore throat, fever, general malaise [leukopenia]
- •nasal bleeding, gum bleeding, subcutaneous bleeding in limbs [thrombocytopenia]
- •general malaise, loss of appetite, yellowing in skin and mucosa [hepatic dysfunction, jaundice]

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

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