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

Internal Revised: 10/2020

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: Takecab Tablets 20mg [agents for digestive organ]

Active ingredient: Vonoprazan fumarate

**Dosage form:** faint red oval tablet, major axis: 11.2 mm, minor axis: 6.2 mm, thickness

Imprint or print on wrapping:(Face)タケキャブ 20mg, (Back)タケキャブ 20

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#### Effects of this medicine

This medicine inhibits the proton pump in a potassium ion-competitive manner to reduce gastric acid secretion in the stomach.

It is usually used to treat gastric/duodenal ulcer, reflux esophagitis 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 have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods. If you have: liver/renal 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))
- <u>Gastric/duodenal ulcer or reflux esophagitis</u>: In general, for adults, take 1 tablet (20 mg of vonoprazan) at a time, once a day. Duration of taking the medicine is up to 8 weeks for gastric ulcer; 6 weeks for duodenal ulcer. To treat reflux esophagitis, in general, duration of taking the medicine is up to 4 weeks. If the effect is insufficient, the treatment may be continued for up to 8 weeks.

Maintenance therapy for repeatedly relapsing reflux esophagitis: In general, for adults, take 0.5 tablet (10 mg of vonoprazan) at a time, once a day. If the effect is insufficient, the dosage may be increased to 1 tablet (20 mg) at a time.

Suppression of recurrence of gastric/duodenal ulcers associated with low-dose aspirin or non-steroidal anti-inflammatory drug therapy: In general, for adults, take 0.5 tablet (10 mg of vonoprazan) at a time, once a day. In any case, strictly follow the instructions.

- If you miss a dose, take the missed dose as soon as possible. In such instance, let more than 8 hours pass before the next dose. 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 constipation, diarrhea, enlarged feeling of abdomen, nausea, rash and edema. 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.

- ·ill feeling, diaphoresis, breathing difficulty, rash, facial edema, convulsion [shock, anaphylaxis]
- •general malaise, fever, shortness of breath, nose bleeding/subcutaneous bleeding [pancytopenia, agranulocytosis, decreased white blood cell, decreased platelets]
- •general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]
- •fever, general malaise, rash/redness of the skin, eyes and oral cavity [toxic epidermal necrolysis, muco-cutaneo-ocular syndrome, erythema multiforme]

## 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 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.