## 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: Camostat Mesilate Tablets 100mg "Nichiiko"

Active ingredient: Camostat mesilate

Dosage form: white tablet, diameter 6.6mm, thick 3.5mm

Imprint or print on wrapping:カモスタットメシル酸塩錠 100mg「日医工」,カモスタッ

ト,100mg,NICHI-IKO,n207,Camostat Mesilate 100mg,「日医工」



#### Effects of this medicine

This medicine suppresses the function of proteolytic enzyme secreted from pancreas. It consequently eases abdominal pain and nausea caused by chronic pancreatitis, and the symptoms of heartburn and reflux symptoms after surgery of stomach.

It is usually used in the treatment of acute symptoms of chronic pancreatitis and postoperative reflux esophagitis.

## 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 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>Chronic pancreatitis:</u> In general, take 2 tablets (200 mg of the active ingredient) at a time 3 times a day. It should be adjusted according to symptoms of the patient.
- <u>Postoperative reflux esophagitis:</u> In general, take 1 tablet (100 mg of the active ingredient) at a time 3 times a day after each meal.
- Strictly follow the instructions in any case.
- •If you miss a dose, take a dose as soon as possible when you remembered that you missed a dose. 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 itch, rash, nausea, abdominal discomfort, abdominal distension and diarrhea. 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.

- hypotension, breathing difficulty, itch [shock, anaphylactoid symptoms]
- •bleeding from the nose/ the gums, subcutaneous bleeding [thrombocytopenia]
- generalized fatigability, loss of appetite, yellowing of the skin and the whites of the eyes [liver dysfunction, jaundice]
- •numbness of limbs or lips, muscle weakness, paralysis in the limbs [hyperkalemia]

# 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 humidity.
- •Discard the remainder. Do not store them.

#### For healthcare professional use only

For further information, talk to your doctor or pharmacist.