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

Internal Revised: 12/2022

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,

**Brand name:**Amitiza Capsules 24mcg

Active ingredient:Lubiprostone

**Dosage form:** light orange opaque capsule, major axis: 9.5 mm, minor axis: 6.0 mm

**Imprint or print on wrapping:**  $\mathcal{P} \in \mathcal{F}_{\mathcal{A}}$   $\mathcal{F}_{\mathcal{A}}$   $\mathcal{F$ 

ミティーザ, 24  $\mu$  g, SPI AA, VIATRIS

patients should understand their medication and cooperate with the treatment.

#### Effects of this medicine

This medicine softens stool by stimulating secretion of water in the small intestine, facilitating the movement of stool in the intestinal tract, leading to defecation.

It is usually used to treat chronic constipation (excluding constipation due to organic diseases).

# 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 or are suspected of having intestinal obstruction due to tumor or hernia.
- •If you are pregnant, possibly 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))
- •In general, for adults, take 1 capsule (24 mcg of the active ingredient) at a time, twice a day after breakfast and dinner. The dosage may be decreased according to the symptoms. Strictly follow the instructions.
- •If you miss a 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 diarrhea, nausea, abdominal pain and chest discomfort. 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.

No pertinent entries.

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 at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- •Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

#### For healthcare professional use only

For further information, talk to your doctor or pharmacist.