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

Internal

Revised: 08/2024

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: Fungizone Oral Suspension 100 mg/mL

Active ingredient: Amphotericin B

Dosage form: light orange, thick suspension

Imprint or print on wrapping:

#### Effects of this medicine

This medicine binds to the cell membrane of fungi, leading to changing of the membrane structure and to alteration in cell permeability, resulting in expressing bactericidal action.

It is usually used to abnormal increases of Candida species in gastrointestinal tract.

# 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))
- •In general, for children, take 0.5 to 1 mL [50 to 100 mg (titer) of the active ingredient] at a time after meal, 2 to 4 times a day. Strictly follow the instructions.
- ·Shake thoroughly before taking and take as a uniform suspension.
- For oral candidiasis, spread the medicine widely over the affected area with your tongue and hold it in your mouth for as long as possible before swallowing.
- •If you miss a dose, take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and follow 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

·Your teeth may turn yellow in some cases. However, it can easily be removed by brushing your teeth.

# Possible adverse reactions to this medicine

The most commonly reported adverse reactions include loss of appetite, nausea, vomiting, abdominal bloating, diarrhea, hives, angioedema, fever, rash and itch. 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.

•fever, bloodshot eye, rash/erythema/blister in skin/mucous [toxic epidermal necrolysis, mucocutaneous ocular syndrome]

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. If you do not know how to discard, 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.