

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: Dafclir Tablets 200mg

Active ingredient: Fidaxomicin

Dosage form: pale yellow red tablet, major axis: approx. 13.1 mm, minor axis: approx. 7.0 mm, thickness : approx. 5.1 mm

Print on wrapping: (Face) ダフクリア 200 mg, house-mark,
(Back) ダフクリア 200 mg, 感染性腸炎治療剤, house-mark



Effects of this medicine

This medicine suppresses RNA polymerase necessary for bacterial growth and shows antibacterial activities.

It is usually used for the treatment of infectious enterocolitis (including pseudomembranous colitis) by *Clostridium difficile*.

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((to be written by a healthcare professional))
- In general, for adults, take 1 tablet (200 mg of the active ingredient) at a time, twice a day. Strictly follow the instructions.
- If you miss a dose, please take immediately when you notice. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take two tablets at once.
- 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, nausea, and vomiting. 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.

- rash, itching, angioedema, dyspnea [anaphylaxis]

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 / /

For further information, talk to your doctor or pharmacist.