

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

Internal

Revised: 08/2018

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:Opsumit Tablets 10mg

Active ingredient:Macitentan

Dosage form:white tablet, diameter: 5.5 mm, thickness: 2.6 mm

Print on wrapping:(face) オプスミット 10mg



Effects of this medicine

By suppressing the action of endothelin, an artery contraction substance, this medicine decreases pulmonary arterial blood pressure and simultaneously increases blood flow in pulmonary artery improving shortness of breath and fatigue.

It is usually used to treat pulmonary arterial hypertension.

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 have liver disorder.
- 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 tablet (10 mg of the active ingredient) at a time, once a day. Strictly follow the instructions.
- If you miss a dose, take a 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

- If you have a possibility of pregnancy, receive an explanation from your doctor for understanding the importance of contraception.
- This medicine may cause liver dysfunction or anemia. You should receive tests for liver function and anemia before taking this medicine.
- Refrain from taking any food or tea containing St. John's wort (a kind of herb) with this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, flush, anemia, edema and peripheral 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.

- general malaise, dizziness, ear ringing [anemia]

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. Ask the pharmacy or medical facility how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.