

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

Internal

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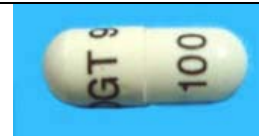
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: BRAZAVES CAPSULES 100mg

Active ingredient: Miglustat

Dosage form: white capsules, major axis: 14 mm, minor axis: 6.5 mm

Print on wrapping: (back) ブレーザベス カプセル 100mg, BRAZAVES capsules 100mg



Effects of this medicine

This medicine blocks glucosylceramide synthesis and suppresses excessive accumulation of lipid in the brain. It consequently improves disorders of eye movement, food swallowing, walking and mental ability. It is usually used to treat Niemann–Pick disease type C.

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, 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 2 capsules (200 mg of the active ingredient) at a time, 3 times a day. For children, for patients with under 0.47 m² of BSA, 1 capsule at a time, once a day, for patients with over 0.47 m² to 0.73 m² of BSA, take 1 capsule at a time, twice a day, for patients with over 0.73 m² to 0.88 m² of BSA, take 1 capsules at a time, 3 times a day, for patients with over 0.88 m² to 1.25 m² of BSA, take 2 capsules at a time, twice a day, for patients with over 1.25 m² of BSA, take 2 capsules at a time, 3 times a day. The dosage may be adjusted according to your symptoms. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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

- This medicine may cause light headedness. Avoid operating dangerous machinery, such as driving a car.
- Patients with renal dysfunction will receive periodical renal function tests to adjust the dosage. Keep all designated test schedules.
- During the treatment, periodic nerve test and blood test are performed to detect adverse reactions. For patients during development, height/weight measurements are also performed. Keep all designated test schedules.
- Male patients who wish to have a child, consult with your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, abdominal bloating, abdominal pain, loss of appetite, vomiting, stomach discomfort, decreased body weight, shivering, sleepiness, spastic paralysis (rigidity, stiffness or paralysis of muscles), rash, sleep disorder and hypothyroidism (feeling cold easily, facial 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.

- watery stool, muddy stool, severe stomachache [severe diarrhea]

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.