

## 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:** Sephience Granules 250mg

Active ingredient: Sepiapterin

Dosage form: Yellow to orange granules

Imprint or print on wrapping: セピエンス 顆粒分包 250mg, 250mg, 1.0 g/包



### **Effects of this medicine**

This medicine lowers the blood phenylalanine level by increasing the substance (BH<sub>4</sub>) that helps the enzyme to metabolize phenylalanine into tyrosine in the cells. It is usually used to treat phenylketonuria.

### **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 experienced any allergic reactions to the ingredients of this medicine in the past.
- If you have malnutrition due to inability to eat or for other reasons.
- If you have any allergic reactions to Sapropterin Hydrochloride.
- If you are elderly patients
- If you are pregnant or breastfeeding
- If you are using other medicines (There is a possibility that medicines may strengthen or weaken efficacy of drugs, you should also be careful for non-prescription medicines).

### **Dosage schedule (How to take this medicine)**

- **Your dosing schedule prescribed by your doctor is ((** :to be written by a healthcare professional))
- In general, take following dose once a day after meal or with meal. This product contains 250 mg of the active ingredient per sachet (1 g). You must take this medicine as directed.

Age	Daily dose
0 to <6 months	7.5 mg/kg
6 months to <1 year	15 mg/kg
1 year to <2 years	30 mg/kg
≥ 2 years	60 mg/kg

- Do not take the medicine as granules. Mix it with water, apple juice or soft food (applesauce or strawberry jam).
- If the doctor judges it necessary, the dose may be reduced or increased again after the reduction.
- If you forget to take a dose, take one dose as soon as you remember. However, if you realize it the next day, skip the missed dose and take the next dose. Do not take two doses at the same 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.
- Treatment may be interrupted or discontinued if the doctor considers that there are concerns about the efficacy or safety.

### **Precautions while taking this medicine**

- Please be sure to follow the instructions if dietary therapy is prescribed .

### **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include diarrhoea, faeces discoloured, and headaches. 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.**

There is no applicable description.

**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 at room temperature (1 to 30 degree Celsius) away from direct sunlight and moisture.
- If any medicine remains, please discard it without storing it. If you do not know how to dispose of it, please consult the pharmacy or medical institution where you receive it. Please do not give it to others.

### **For healthcare professional use only**

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For further information, talk to your doctor or pharmacist.