

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

Internal

Revised: 12/2022

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: VFEND Tablets 50mg**Active ingredient:** Voriconazole**Dosage form:** white tablet, diameter: 7.0 mm, thickness: 3.6 mm**Imprint or print on wrapping:** VFEND 50mg, ブイフェンド 50mg, Pfizer VOR 50**Effects of this medicine**

This medicine shows the effect against fungal infections in the body, by inhibiting biosynthesis of cell membrane component of fungi (a kind of mold).

It is usually used to treat severe/refractory fungal infections (e.g. aspergillosis, candidiasis and cryptococcosis) and to prevent deep mycosis in patients undergoing hematopoietic stem cell transplantation.

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 reduced liver function.
If you have arrhythmia or are in a condition easy to develop arrhythmia.
- 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))
- For adults (with body weight 40 kg or over): In general, start with 6 tablets (300 mg of the active ingredient) at a time, twice a day on the first day. From the second day on, take 3 or 4 tablets (150 mg or 200 mg) at a time, twice a day between meals. The dosage may be increased according to the condition or if the effect is insufficient. The maximum daily dose is 8 tablets (400 mg) at a time, twice a day on the first day and 6 tablets (300 mg) at a time, twice a day after the second day.
For adults (with body weight less than 40 kg): In general, start with 3 tablets (150 mg of the active ingredient) at a time, twice a day on the first day. From the second day on, take 2 tablets (100 mg) at a time, twice a day between meals. The dosage may be increased up to 3 tablets (150 mg) at a time, twice a day after the second day according to the condition or if the effect is insufficient.
For children (2 to less than 12 years or 12 years or over with body weight less than 50 kg): In general, after the treatment with voriconazole injection, take 9 mg per kilogram of the body weight (mg/kg) of the active ingredient at a time, twice a day between meals. The dosage may be increased by 1 mg/kg at a time according to the condition or if the effect is insufficient. The maximum daily dose is 7 tablets (350 mg) at a time, twice a day. The dosage may be decreased by 1 mg/kg at a time if this medicine is not well-tolerated (if it is impossible to continue the treatment). [If the maximum dosage of 7 tablets (350 mg) at a time has been taken, the dosage may be decreased by 1 tablet (50 mg) at a time.]
For children (12 years or over with body weight 50 kg or over): In general, after the treatment with voriconazole injection, take 4 tablets (200 mg of the active ingredient) at a time, twice a day between meals. The dosage may be increased up to 6 tablets (300 mg) at a time, twice a day according to the condition or if the effect is insufficient. This preparation contains 50 mg of the active ingredient in a tablet. In any case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. 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

- When using this medicine, blood, renal function, liver function and electrocardiogram tests are periodically performed.
- This medicine may cause sensitivity to bright light, blurred vision and difficulty seeing, which may continue after you cancel the medication. During the treatment or after you cancel the medication, avoid operating dangerous machinery, such as driving a car, unless these symptoms disappear. In addition, see an ophthalmologist if necessary.
- Since this medicine may cause photosensitivity reaction (redness of skin exposed to light), avoid exposure to sunlight by wearing long-sleeved clothes, hat, etc. and exposure to ultraviolet rays by using a highly effective

sunscreen. In addition, pay attention in the same way for the time being even after using this medicine. If you notice abnormalities, do not expose the affected area to light and consult with your doctor or pharmacist immediately. You may receive instruction to see a dermatologist periodically if necessary.

- When taking this medicine concomitantly with warfarin, you may need to take blood test more frequently to check bleeding tendency.
- Avoid taking any food containing St. John's wort (a kind of herb) with this medicine, since it may diminish medicinal effects.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include photophobia (sensitive to bright light), foggy vision (blurred vision), vision disorder, nausea, vomiting, loss of appetite, headache and insomnia. 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.

- cold sweat, paleness of the face, breathing difficulty [shock, anaphylaxis]
- high fever, skin redness, stomatitis [toxic epidermal necrosis, Stevens-Johnson syndrome, erythema multiforme]
- general malaise/loss of appetite, yellowing of the skin and the white of eyes, coma [liver disorder]
- chest pain, palpitation, irregular pulse [electrocardiogram QT prolongation, ventricular tachycardia, ventricular fibrillation, arrhythmia, complete atrioventricular block]
- general malaise, respiratory distress, general edema [heart failure]

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 reach of children. Store at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, 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.