

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

Internal
Revised: 04/2022

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: Vyndaqel capsules 20mg

Active ingredient: Tafamidis meglumine

Dosage form: yellow capsule, major axis: approx. 21 mm, minor axis: approx. 8 mm

Imprint or print on wrapping: ビンダケル, 20, VYN 20, Vyndaqel 20mg



Effects of this medicine

This medicine suppresses amyloid formation by stabilizing bind to TTR (transthyretin).

It is usually used to suppress progress of peripheral neuropathy of transthyretin familial amyloid polyneuropathy and to treat transthyretin amyloid cardiomyopathy (wild and variant type).

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 liver dysfunction.
- 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))
- For transthyretin familial amyloid polyneuropathy: In general, for adults, take 1 capsule (20 mg of the active ingredient) at a time, once a day.
For transthyretin amyloid cardiomyopathy: In general, for adults, take 4 capsules (80 mg of the active ingredient) at a time, once a day. If not tolerated, the dosage may be decreased.
In any case, strictly follow the instructions.
- If you have transthyretin amyloid cardiomyopathy and the medicine containing tafamidis free acid 61 mg (Vynmac capsules) is not tolerated, this medicine will be used instead of that for dose reduction. As well, this medicine may be changed to the medicine containing tafamidis free acid 61 mg (Vynmac capsules) in some cases. Since the number of capsules you need to take per day should be changed, you should receive an explanation to fully understand about the change and pay attention not to take wrong dose.
- If you miss a dose, take the missed dose as soon as possible. However, if you noticed it on and after the next day, skip the missed dose. 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

- Avoid pregnancy while you or your partner are taking this medicine and for a month after you or your partner take the last dose of this medicine. In addition, if you or your partner become pregnant while treatment with this medicine, consult with your doctor immediately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, urinary tract infection, nausea and headache. 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.

No pertinent entries.

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. Please consult with your pharmacy or medical institution, since proper disposal of the unused medicines requires attention. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.