

Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Tafamidis 61 mg Soft Gelatin Capsules

VyndaMx[®]

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What VyndaMx[®] (Tafamidis) is and what it is used for
2. What you need to know before you take VyndaMx[®] (Tafamidis)
3. How to take VyndaMx[®] (Tafamidis)
4. Possible side effects
5. How to store VyndaMx[®] (Tafamidis)
6. Contents of the pack and other information

1. What VyndaMx[®] (Tafamidis) is and what it is used for

VyndaMx[®] (Tafamidis) contains the active substance Tafamidis.

VyndaMx[®] (Tafamidis) is a medicine that treats a disease called transthyretin amyloidosis. Transthyretin amyloidosis is caused by a protein called transthyretin (TTR) that does not work properly. TTR is a protein that carries other substances, such as hormones, through the body.

In patients with this disease, TTR breaks up and may form fibers called amyloid. Amyloid can build up around your heart and in other places in your body. The deposition of the amyloid in the organ such as heart causes the symptoms of this disease. When this occurs, it prevents them from working normally.

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VyndaMx[®] Soft gelatin capsules
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VyndaMx[®] (Tafamidis), can prevent TTR from breaking up and forming amyloid fibrils. This medicine is used to treat wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).

2. What you need to know before you take VyndaMx[®] (Tafamidis)

Do not take VyndaMx[®] (Tafamidis)

If you are allergic to VyndaMx[®] (Tafamidis) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, before taking VyndaMx[®] (Tafamidis).

- Women that can become pregnant should use birth control while taking VyndaMx[®] (Tafamidis) and should continue using birth control for one month after stopping treatment with VyndaMx[®] (Tafamidis). There are no data on the use of VyndaMx[®] (Tafamidis) in pregnant women.
- You should not take Tafamidis if you are pregnant or breast-feeding.
- An increase in liver function tests and a decrease in thyroxine may occur.

Other medicines and VyndaMx[®] (Tafamidis)

Tell your doctor if you are taking, have recently taken or might take any other medicines.

You should inform your doctor or pharmacist if you are taking any of the following:

- Non-steroidal anti-inflammatory drugs
- Diuretic medicines (e.g. furosemide, bumetanide)
- Anti-cancer medicines (e.g. methotrexate, imatinib)
- Statins (e.g. rosuvastatin)
- Anti-viral medicines (e.g. oseltamivir, tenofovir, ganciclovir, adefovir, cidofovir, lamivudine, zidovudine, zalcitabine)
- Products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- You should not take VyndaMx[®] (Tafamidis) if you are pregnant or breast-feeding.
- If you are able to become pregnant, you must use birth control during treatment and for one month after stopping treatment.

Driving and using machines

VyndaMx[®] (Tafamidis) is believed to have no or negligible influence on the ability to drive and use machines.

VyndaMx[®] (Tafamidis) contains sorbitol

This medicine contains no more than 44 mg sorbitol in each capsule. Sorbitol is a source of fructose.

3. How to take VyndaMx[®] (Tafamidis)

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is one VyndaMx[®] (Tafamidis) 61 mg capsule taken once a day.

If you vomit after taking this medicine and can identify the intact VyndaMx[®] (Tafamidis) capsule, then an additional dose of VyndaMx[®] (Tafamidis) should be taken in the same day; if you cannot identify the VyndaMx[®] (Tafamidis) capsule, then no additional dose of VyndaMx[®] (Tafamidis) is necessary, and you can resume taking VyndaMx[®] (Tafamidis) the next day as usual.

Method of administration

VyndaMx[®] (Tafamidis) is for oral use.
The soft gelatin capsule should be swallowed whole, not crushed or cut.
The capsule may be taken with or without food.

Instructions for opening the blisters

To remove capsule from the individual blister, push capsule through the aluminum foil.

If you take more VyndaMx[®] (Tafamidis) than you should

You should not take more capsules than your doctor tells you to. If you take more capsules than you have been told to take, contact your doctor.

If you forget to take VyndaMx[®] (Tafamidis)

If you forget to take a dose, take your capsules as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking VyndaMx[®] (Tafamidis)

Do not stop taking VyndaMx[®] (Tafamidis) without first speaking to your doctor. As VyndaMx[®] (Tafamidis) works by stabilising the TTR protein, if you stop taking VyndaMx[®] (Tafamidis), the protein will no longer be stabilised, and your disease may progress.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Flatulence and Liver function test increased are the side effects observed with the use of VyndaMx[®] (Tafamidis).

If you are taking this medicine, it may increase in liver function tests and may decrease total serum thyroxine without accompanying change in free thyroxine (T4) or thyroid stimulating hormone (TSH).

5. How to store VyndaMx[®] (Tafamidis)

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister card and on the carton.

Store at or below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your doctor how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What VyndaMx[®] (Tafamidis) contains

- The active substance is Tafamidis. Each soft gelatin capsule contains 61 mg micronized Tafamidis.
- The other ingredients are: Each soft gelatin capsule contains no more than 44 mg of sorbitol (E 420).

What VyndaMx[®] (Tafamidis) looks like and contents of the pack

VyndaMx[®] (Tafamidis) soft gelatin capsules are reddish brown, opaque, oblong (approximately 21 mm) printed with “VYN 61” in white. VyndaMx[®] (Tafamidis) is available in two pack sizes of PVC/PA/alu/PVC-alu/PET/Paper perforated unit dose blisters: a pack of 30 soft gelatin

capsules (3 strips of 10 soft gelatin capsules each) (3X10) and a multipack of 90 (3 packs of 30 x 1) soft gelatin capsules.

Not all pack sizes may be marketed in your country.

Imported and marketed by

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