Package leaflet: Information for the user
Vyndaqel 20 mg soft capsules
tafamidis meglumine

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vyndaqel is and what it is used for

Vyndaqel contains the active substance tafamidis.

Vyndaqel is a medicine which 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 fibres called amyloid. Amyloid can build up around your nerves (known as transthyretin amyloid polyneuropathy or ATTR-PN) and in other places in your body. The amyloid causes the symptoms of this disease. When this occurs, it prevents them from working normally.

Vyndaqel, can prevent TTR from breaking up and forming amyloid. This medicine is used to treat adult patients with this disease whose nerves have been affected (people with symptomatic polyneuropathy) to delay further progression.

2. What you need to know before you take Vyndaqel

Do not take Vyndaqel

If you are allergic to tafamidis meglumine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Vyndaqel.

- Women that can become pregnant should use birth control while taking Vyndaqel and should continue using birth control for one month after stopping treatment with Vyndaqel. There are no data on the use of Vyndaqel in pregnant women.

Children and adolescents

Children and adolescents do not have the symptoms of transthyretin amyloidosis. Vyndaqel is therefore not used for children and adolescents.

Other medicines and Vyndaqel

Tell your doctor or pharmacist 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)

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 Vyndaqel 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

Vyndaqel is believed to have no or negligible influence on the ability to drive and use machines.

Vyndaqel contains sorbitol

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

3. How to take Vyndaqel

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

The recommended dose is one Vyndaqel 20 mg (tafamidis meglumine) capsule taken once a day.

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

<u>Method of administration</u>

Vyndaqel is for oral use.
The soft capsule should be swallowed whole, not crushed or cut.

The capsule may be taken with or without food.

Instructions for opening the blisters

- Tear off one individual blister from the blister card along the perforated line.
- Push capsule through the aluminium foil.

If you take more Vyndaqel 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 Vyndaqel

If you forget to take a dose, take your capsules as soon as you remember. If it is within 6 hours before your next dose, skip the missed dose and take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Vyndaqel

Do not stop taking Vyndaqel without first speaking to your doctor. As Vyndaqel works by stabilising the TTR protein, if you stop taking Vyndaqel, 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.

Very common: may affect more than 1 in 10 people are listed below:

- Diarrhoea
- Urinary tract infection (symptoms may include: pain or a burning sensation when you urinate or a frequent need to urinate)
- Stomach ache or abdominal pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vyndaqel

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. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

6. Contents of the pack and other information

What Vyndaqel contains

- The active substance is tafamidis. Each capsule contains 20 mg micronized tafamidis meglumine equivalent to 12.2 mg tafamidis.

- The other ingredients are: gelatine (E 441), glycerine (E 422), sorbitol (E 420) [see section 2 "Vyndaqel contains sorbitol"], mannitol (E 421), sorbitan, yellow iron oxide (E 172), titanium dioxide (E 171), purified water, macrogol 400 (E 1521), sorbitan monooleate (E 494), polysorbate 80 (E 433), ethyl alcohol, isopropyl alcohol, polyvinyl acetate phthalate, propylene glycol (E 1520), carmine (E 120), brilliant blue FCF (E 133) and ammonium hydroxide (E 527).

What Vyndaqel looks like and contents of the pack

Vyndaqel soft capsules are yellow, opaque, oblong (approximately 21 mm) printed with "VYN 20" in red. Vyndaqel is available in two pack sizes of PVC/PA/alu/PVC-alu perforated unit dose blisters: a pack of 30 x 1 soft capsules and a multipack of 90 soft capsules comprising of 3 cartons, each containing 30 x 1 soft capsules. Not all pack sizes may be marketed.

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Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Telephone 01304 616161.

This leaflet was last revised in 04/2024.

This medicine has been authorised under 'exceptional circumstances'.
This means that because of the rarity of this disease it has been impossible to get complete information on this medicine.

Any new information on this medicine will be reviewed every year and this leaflet will be updated as necessary.

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