Tafamidis Meglumine Te Arai

Tafamidis Meglumine (as Tafamidis)

20 mg Soft Capsule

What is in this leaflet

Please read this leaflet carefully before you start using Tafamidis Meglumine Te Arai.

This leaflet answers some common questions about Tafamidis Meglumine Te Arai. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tafamidis Meglumine Te Arai against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Tafamidis Meglumine Te Arai is used for

Tafamidis Meglumine Te Arai contains the active substance tafamidis meglumine.

Tafamidis meglumine 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), between cells in your heart (known as transthyretin amyloid cardiomyopathy or ATTR-CM), and in other places in your body. The amyloid causes the symptoms of this disease. When this occurs, it prevents the nerves or heart from working normally.

Tafamidis meglumine, 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. This medicine is also used to treat adult patients whose heart has been affected (people with symptomatic cardiomyopathy).

Your doctor may have prescribed Tafamidis Meglumine Te Arai for another reason.

Ask your doctor if you have any questions about why Tafamidis Meglumine Te Arai has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use tafamidis meglumine

When you must not use it

Do not use Tafamidis Meglumine Te Arai if:

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

Tafamidis Meglumine Te Arai should not be used in children and adolescents.

If you are not sure whether you should start using Tafamidis Meglumine Te Arai, talk to your doctor.

Before you start to use it

Tell your doctor if:

- you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Women that can become pregnant should use birth control while taking tafamidis meglumine and should continue using birth control for one month after stopping treatment with tafamidis meglumine. There are no data on the use of tafamidis meglumine in pregnant women.

If you have not told your doctor about any of the above, tell them before you start using Tafamidis Meglumine Te Arai.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking tafamidis meglumine.

Some medicines may interfere with tafamidis meglumine. These include:

- non-steroidal anti-inflammatory drugs (such as ibuprofen, diclofenac, naproxen)
- diuretic medicines (such as furosemide, bumetanide)
- anti-cancer medicines (such as methotrexate, imatinib)
- statins (such as atorvastatin, simvastatin, pravastatin, rosuvastatin)
- anti-viral medicines (such as oseltamivir, tenofovir, ganciclovir, adefovir, cidofovir, lamivudine, zidovudine, zalcitabine)

These medicines may be affected by tafamidis meglumine or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Tafamidis Meglumine Te Arai.

How to use tafamidis meglumine

How much to take

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

For patients with transthyretin amyloid polyneuropathy (ATTR-PN) the recommended dose of Tafamidis Meglumine Te Arai is one capsule (20 mg) orally once a day.

For patients with transthyretin amyloid cardiomyopathy (ATTR-CM), the recommended dose of Tafamidis Meglumine Te Arai is four capsules (80 mg) orally once a day

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

Method of administration
Tafamidis Meglumine Te Arai 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.

How long to take it

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

If you forget to take it

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.

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.

While you are using tafamidis meglumine

Things you must do

If you are able to become pregnant, you must use birth control during treatment and for one month after stopping treatment.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Tafamidis Meglumine Te Arai.

Things you must not do

Do not give Tafamidis Meglumine Te Arai to anyone else, even if they have the same condition as you.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Tafamidis Meglumine Te Arai.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using tafamidis meglumine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Common and very common are listed below (may affect more than 1 in 10 people):

- 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
- Rash, itching

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using tafamidis meglumine

Storage

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

Do not use this medicine after the expiry date (EXP) 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.

Disposal

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.

Product description

What it looks like

Tafamidis Meglumine Te Arai are yellow to pale yellow, oblong (approximately 21 mm) soft capsule, imprinted with “LP678” in red. Capsule contains white to pink colored suspension.

Tafamidis Meglumine Te Arai is available in a pack of 30 soft capsules contained in OPA/Al/PVC – Paper/PET/Al perforated blisters.

Ingredients

Active ingredient:

Each capsule contains 20 mg micronized tafamidis meglumine equivalent to 12.2 mg tafamidis.

Inactive ingredients:

The other ingredients are: gelatine (E 441), glycerine (E 422), sorbitol (E 420), sorbitan oleate, ferric oxide (E 172), titanium dioxide (E 171), water purified, macrogol 400 (E 1521), polysorbate 80 (E 433), ethanol, propylene glycol (E 1520), carmine (E 120), shellac, ammonium hydroxide (E 527) and simeticone.

Sponsor Details

Tafamidis Meglumine Te Arai is supplied in New

Zealand by: Te Arai BioFarma Limited

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NEW ZEALAND

0800 832 724

Date of Preparation

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