



Tafamidis is a novel transthyretin stabilizer which is PBS listed for the treatment of **transthyretin cardiac amyloidosis**. There is only one dosage (**61mg / one tablet daily**) available in Australia. Patients should be instructed not to cut/crush the tablet.

For more information, please review the full PBS listing and product information for tafamidis:

- <https://www.pbs.gov.au/medicine/item/14100D>
- <https://www.tga.gov.au/resources/artg/314813>

Requirements to Prescribe

- Aged 18 years of age or older
- Transthyretin amyloid cardiomyopathy (ATTR-CM)
- Evidence of cardiac involvement with an end-diastolic interventricular septal wall thickness ≥ 12 mm
- Documentation that AL amyloidosis has been excluded
- New York Heart Association Class I or II heart failure

Contraindications to Prescribe

- Severe renal impairment (CrCl ≤ 30 mL/min, eGFR < 25)
- Severe liver impairment (transaminases $> 2.0 \times$ ULN)
- Established (> 3 months) NYHA Class III or IV* heart failure
- Pregnancy / women of childbearing potential not using contraception
- Women who are breastfeeding
- Paediatric patients (aged < 18 years)
- Organ transplant recipient
- Implanted cardiac ventricular assist device

**If a patient's heart failure has worsened to NYHA class III/IV, the prescriber must review the patient within 3 months to determine if worsening is persistent. No more than two repeat prescriptions should be issued in such an instance.*

Medication Interactions

Tafamidis has the potential to **inhibit the efflux transporter BCRP** which may cause increased patient exposure to the following drugs if taken concurrently:

- **Statins**
- **Methotrexate, sulfasalazine, leflunomide**
- **Tyrosine kinase inhibitors i.e. imatinib**
- **Anthracyclines**

Prescribers should monitor patients for potential toxicity and consider dose reduction as needed.

Suggested Monitoring

Below is the current St Vincent's Hospital Sydney protocol for the initiation and monitoring of patients on tafamidis:

Initiation EUCs, LFTs, hsTropI, NTproBNP

One Month EUCs, LFTs

Six Monthly EUCs, LFTs

Current Australian and International Amyloidosis Guidelines also recommend all patients with cardiac amyloidosis undergo annual:

- **Cardiac biomarkers:** hsTropI, NTproBNP
- **Echocardiogram:** wall thickness, GLS
- **Ambulatory cardiac monitoring** i.e. Holter

Side Effects

In clinical trials, the following symptoms were reported more frequently in patients treated with tafamidis vs placebo:

- Feeling weak or a lack of energy
- Feeling unbalanced when standing or walking
- Sinusitis/nasal congestion
- Flatulence or diarrhoea
- Muscle or joint pain
- Skin ulcers
- Cataracts
- Cystitis
- Excessive sweating



For more information or individual patient advice:

1. Visit our website via the QR code
2. Email us at amyloidreferrals@svha.org.au
3. Telephone the St Vincent's Hospital switchboard (p) 8382 1111 and ask for the Cardiac Amyloidosis Fellow