

Temporary Methotrexate shortage

A temporary shortage of methotrexate is currently affecting the following:

ARX-METHOTREXATE 10 methotrexate 10 mg tablet blister pack (until 21 Feb 2025)

Additionally, Pfizer is making changes to their methotrexate product line:

- The METHOBLASTIN methotrexate 10mg tablet (<u>bottle</u>) is being replaced by METHOBLASTIN methotrexate 10mg tablet (blister)
- New blister pack sizes are available as 10, 50 tablets.
- The discontinuation of the old presentation may result in a reduction in supply until supply is exhausted.

For further information, please see Pfizer Product Change Notice.

Patient Guidance: Despite these shortages, alternative brands remain available, and the overall supply should not be significantly disrupted. Patients should be advised that they may need to switch to an alternative brand temporarily. Encourage them to consult with their pharmacist if they have any questions or concerns.

For more information, please see TGA - methotrexate medicine shortage information.

For any concerns related to medication shortages, please contact Bill Renton, Chair of the ARA Therapeutics Committee, at wdrenton@gmail.com.

Nov PBS Changes to rheumatology medicines

As of 1 November 2024, there have been several important updates to PBS listings for rheumatology medicines:

- **Romosozumab** (Evenity) is now PBS listed for **severe established osteoporosis** as first-line therapy. Authority applications for initial, grandfather and continuing treatments can be made using the Online PBS Authorities system or by phone.
- **Methotrexate** (Methoblastin) 10mg tablet, 10 tablet blister (new formulation, previously 15mg bottle) is now listed on the PBS as an unrestricted benefit.
- **Adalimumab** is now TGA listed for the treatment of chronic non-infectious anterior uveitis in paediatric patients 2 years of age and older who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

For further details, please see **Services Australia - PBS Listing 1 Nov.**

TGA Consultation on Medicine shortages and discontinuations: Proposed changes to reporting requirements

The Therapeutic Goods Administration (TGA) has <u>announced</u> proposed improvements to the management of medicine shortages and discontinuations in Australia. Your feedback will help to inform priority areas for the TGA to further reduce the impact of medicine supply disruptions.

The initial focus is to update TGA's medicine shortages regulatory framework to better meet public information needs. This includes proposals to:

- Add critical non-prescription medicines to the list of reportable medicines, which would require sponsors of those medicines to report shortages and discontinuations to the TGA.
- Update the *Therapeutic Goods Act 1989* to enable the TGA to require detailed supply information from sponsors of any medicines, not just reportable medicines.
- Require sponsors to provide 12 months' notice to the TGA of a decision to permanently discontinue supply of any reportable medicine in Australia.

The TGA consultation on these proposals, <u>Medicine shortages and discontinuations:</u> <u>proposed changes to reporting requirements</u>, is now open and will close **13 January 2025**.

We value your feedback and welcome your comments. To share your thoughts, please reach out to Bill Renton, Chair of the ARA Therapeutics Committee, at wdrenton@gmail.com.

If you have any questions on any of the above items, please contact Jing Ye, ARA Clinical Project Officer at project@rheumatology.org.au.