

28th March 2021

**Macrobid® (nitrofurantoin macrocrystals/nitrofurantoin monohydrate) Modified Release Capsule
100mg release characteristics and in-use shelf life.**

Dear Healthcare Professional,

Te Arai BioFarma Limited would like to inform you of the following:

Summary

- Macrobid® has unique release properties which differ from immediate release nitrofurantoin microcrystalline tablets (Nifuran®).
- The in-use shelf life of Macrobid® is 90 days.

Background

Macrobid® is an antibacterial agent for the acute treatment of uncomplicated urinary tract infections. Macrobid® is fully funded by PHARMAC in Sections B and H of the Pharmaceutical Schedule.

Each Macrobid® capsule contains two forms of nitrofurantoin. Twenty-five percent is macrocrystalline nitrofurantoin, which has slower dissolution and absorption than nitrofurantoin microcrystals. The remaining 75% is nitrofurantoin monohydrate contained in a powder blend which, upon exposure to gastric and intestinal fluids, forms a gel matrix that releases nitrofurantoin over time.

As a result of the unique release properties of nitrofurantoin macrocrystals and nitrofurantoin monohydrate, Macrobid® can be dosed less often than nitrofurantoin microcrystalline tablets (Nifuran®), while being equally effective in the acute treatment of uncomplicated urinary tract infections.

Dosing for acute treatment of uncomplicated urinary tract infections in Adults and Paediatric Patients Over 12 Years:

- Macrobid®: One 100 mg capsule every 12 hours.
- Nifuran®: Usual dose 50-100 mg four times daily.

Macrobid® should be specified by brand when prescribing to avoid any confusion between modified release capsules and immediate release tablets.

Before prescribing, please review the full Macrobid® Data Sheet available at www.medsafe.govt.nz.

Macrobid® is supplied in a pharmacy dispensing bottle containing 100 capsules. On 23 February 2021, Medsafe approved an in-use shelf life of 90 days for Macrobid®.

Please note, PHARMAC has temporarily applied the Wastage rule to Macrobid®. This means that pharmacies can claim wastage for any unused stock of Macrobid® once it has expired due to the in-use shelf life.

Further information

If you have any questions or require additional information regarding the use of MacroBID® please email regulatory@tearaibiofarma.com.

Reporting adverse events

Please report any suspected adverse events via email to adverse.event@tearaibiofarma.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at <https://nzphvc.otago.ac.nz/reporting> or by email to nzphvc@otago.ac.nz.

Yours sincerely,



Julia Reese

Director of Regulatory Affairs

Te Arai BioFarma Limited

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