

Department of Health Therapeutic Goods Administration

SERIOUS SHORTAGE MEDICINE SUBSTITUTION NOTICE

Notice Reference Number: SSN 20-01

This Notice applies for the following dates:

From: 13/05/2020 To: 31/07/2020

This Notice applies only to the following medicine

Name of medicine (including strength and formulation): *Metformin modified-release* (also known as extended-release or XR) 500mg tablets

Schedule: S4: Prescription Only Medicine

Details of medicine to be supplied under this SSN

Name of medicine (including strength	Metformin immediate-release 500 mg
and formulation) to be supplied	tablets or metformin modified-release
	1000 mg tablets

Same formulation but different strength? Yes, see table below.

Same active but different salt? No

Different dose form? Yes, see table below

Metformin modified-release 500mg dose	Medicine to be supplied
1500 mg daily	Metformin modified-release 1000 mg plus metformin immediate-release 500 mg in separate doses
1000 mg daily	Metformin modified-release 1000 mg
500 mg daily	Metformin immediate-release 500 mg daily*

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 or 02 6232 8644 Fax: 02 6232 8112
Email: info@tga.gov.au https://www.tga.gov.au



*some brands of metformin immediate-release tablets are scored

Any restrictions on this dose form e.g. dose intervals.

Details: When modified-release tablets are supplied, they should be taken at the time of day the patient would usually take their modified-release dose.

Where the result of the substitution is a dosing regimen using modified-release and immediate-release tablets, the timing of the modified-release dose should remain unchanged. The immediate-release dose in the regimen should be taken at a different time from the modified-release dose.

Any limitations on substitution?

• Patients previously intolerant to metformin immediate-release formulations must be referred to the prescriber if the relevant substitution includes immediate-release metformin

Quantity of this formulation (if applicable): See 'Conditions' below

Conditions:

- Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription.
- The patient must present with a valid prescription for the medicine to be substituted for.
- The patient/carer must consent to receiving the medicine(s) supplied pursuant to the notice.
- The pharmacist may, in their professional judgement, determine that the patient is not suitable to receive alternative medicine under the notice e.g. known previous hypersensitivity or severe adverse reaction to excipients; known previous intolerance to immediate-release metformin formulations.