



Health

POISONS AND THERAPEUTIC GOODS REGULATION 2008

ORDER

Authorisation to supply a restricted substance - metformin

I, Bruce Battye, Deputy Chief Pharmacist, a duly appointed delegate of the Secretary, NSW Health, make this instrument pursuant to clause 42A(1)(a) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) [the Regulation]. Pursuant to clause 42A(2) of the Regulation, the authorisation is granted subject to conditions.

BRUCE BATTYE
Deputy Chief Pharmacist
(Delegation Number PH626)

Date:

29 JUL 2020

Authorisation to supply a form of the restricted substance metformin instead of the form prescribed that is a medicine in short supply (short supply medicine)

1 Authorisation

This order authorises a pharmacist to supply the corresponding listed form of metformin on the prescription of an authorised practitioner where the form of metformin prescribed is in short supply (Short Supply Medicine), as notified by the Therapeutic Goods Administration's Serious Shortage Medicine Substitution Notice, Reference Number SSSN 20-02:

Daily dose of metformin modified release 500mg tablets	Medicine to be supplied
1500 mg (3 tablets) daily	One metformin modified release 1000 mg tablet plus one metformin immediate release 500 mg tablet daily in separate doses
1000 mg (2 tablets) daily	One metformin modified release 1000 mg tablet daily
500 mg (1 tablet) daily	One metformin immediate release 500 mg tablet daily

2 Conditions

- a. The Short Supply Medicine remains on a current notice that is published by the Therapeutic Goods Administration as a medicine that is in short supply and that may be substituted for the other form of the Short Supply Medicine.
- b. The patient must present with a valid prescription for the medicine to be substituted for.
- c. It is not practicable for the patient to obtain a prescription for the substitute form/s of the medicine from a prescriber before the patient needs the supply of the prescribed medicine
- d. The patient or his/her agent or carer must consent to receiving the medicine/s supplied pursuant to the notice.
- e. The pharmacist must be satisfied that in his/her professional judgement, after taking all reasonable steps to obtain all relevant information including discussing the matter with the prescriber if possible, that the patient is suitable to receive the different form of the medicine under the notice, considering factors such as known previous hypersensitivity or severe adverse reaction to excipients.
- f. The pharmacist must make a reasonable attempt to inform the prescriber of the change to the prescribed medicine, if possible before supplying the medicine.
- g. The total quantity of active drug supplied and the total number of days' treatment supplied must be the same as those specified (explicitly or implicitly) in the prescription.

- h. The pharmacist must label the medicine/s with directions for the same daily dosage of active drug (totalled where two forms are supplied) that was specified in the prescription.
- i. The pharmacist must record full details of the supply in the pharmacy's dispensing record system, including the medicine form prescribed and the medicine form/s which was/were supplied in its place.
- j. The pharmacist must annotate the prescription with details of the form/s of the medicine supplied.
- k. The medicine form/s supplied must be currently registered on the Australian Register of Therapeutic Goods and as supplied by the licensed manufacturer/sponsor. However in order to comply with condition (g), the pharmacist may break or combine ARTG pack/s to make a quantity of tablets of the medicine which differs from the pack size/s specified in the Register.

3 Duration

This authority commences on the day it is signed and dated, and expires on the date that the prescribed medicine ceases to be on a current Serious Shortage Medicine Substitution Notice that is published by the Therapeutic Goods Administration as a medicine that is in short supply and that may be substituted for the other form of the Short Supply Medicine; or otherwise on a date that this authority is revoked.