NSW GOVERNMENT Health

POISONS AND THERAPEUTIC GOODS REGULATION 2008

ORDER

Authorisation to supply a restricted substance – estradiol transdermal patch

I, Judith Mackson, Chief Pharmacist, a duly appointed delegate of the Secretary, NSW Health, make this authorisation 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.

Judith Mackson

JUDITH MACKSON
Chief Pharmacist
(Delegation Number PH626)

Date: 28 August 2020.

Authorisation to supply a preparation of the restricted substance estradiol transdermal patch (Substitute Medicine) instead of the preparation prescribed that is a medicine in short supply (Short Supply Medicine)

1 Authorisation

This order authorises a pharmacist to supply the corresponding listed preparation of estradiol transdermal patch (Substitute Medicine) on the prescription of an authorised practitioner where the preparation of the estradiol transdermal patch prescribed is in short supply (Short Supply Medicine), as notified by the Therapeutic Goods Administration's Serious Shortage Substitution Notice, Reference Number SSSN 20-04:

Short Supply Medicine	Substitute Medicine
ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (ARTG 97566)	**ESTRADERM MX 100** estradiol 100 microgram/24 hours (3mg) transdermal drug delivery system sachet (ARTG 67090) OR **CLIMARA 100** estradiol 100 micrograms/day transdermal drug delivery system sachet (ARTG 56198)

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 preparation 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 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 Substitute Medicine 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 Substitute Medicine, 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 Substitute Medicine.

g. The total quantity of the Substitute Medicine supplied must be equivalent to the number of days supplied on the original prescription. The dose interval varies between brands and if dispensing Climara 100 as the Substitute Medicine, half the number of patches specified in the original prescription for Estradot 100 must be supplied.

h. An estradiol transdermal patch must not be cut or torn.

i. The pharmacist must label the Substitute Medicine with relevant directions for use and the dosage interval, as specified for the relevant Short Supply Medicine in the dosage substitution table below:

Short Supply Medicine	Substitute Medicine
ESTRADOT 100 One patch applied twice a week	**ESTRADERM MX 100** One patch applied twice a week
ESTRADOT 100 One patch applied twice a week	**CLIMARA 100** One patch applied once a week

j. The pharmacist must record full details of the supply in the pharmacy's dispensing record system, including the medicine prescribed and the medicine supplied in its place.

k. The pharmacist must annotate the prescription with details of the medicine supplied.

3 Publication

This Order will be published in the Government Gazette pursuant to clause 42A(1) of the Regulation.

4 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 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 preparation of the Short Supply Medicine, or otherwise on a date that this authority is revoked.