

Department of Health Therapeutic Goods Administration

SERIOUS SHORTAGE SUBSTITUTION NOTICE

| Notice Reference Number | SSSN 20-04 |
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This Notice applies for the following dates

| From | 26/08/2020 | То | 31/12/2020 |
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This Notice applies only to the following medicine

| Name of medicine in shortage (including strength and formulation): | ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (ARTG 97566) |
|--|---|
| Schedule: | S4: Prescription Only Medicine |

Details of medicine to be supplied under this SSSN

| Name of medicine (including strength and formulation) to be supplied | 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) |
|--|---|
| Same formulation but different strength? | No, See dosage substitution table below |
| Same active but different salt? | No |
| Different dose form? | No |

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



Dosage substitution table

| Original medicine dose: ESTRADOT 100 | 1 patch applied twice a week |
|--|---|
| Substitute medicine dose: ESTRADERM MX 100 | 1 patch applied twice a week |
| Substitute medicine dose: CLIMARA 100 | 1 patch applied once a week |
| Any restrictions on this dose form (e.g. dose intervals) | The patch size and dose interval varies between brands. The patch must not be cut or torn. |
| Any limitations on substitution | N/A |
| Quantity of this formulation (if applicable) | If dispensing Climara as the substitute medicine, only half the number of patches specified in the original prescription for Estradot will be required. |

Conditions:

- Total quantity supplied under this protocol must be equivalent to the number of days supplied on original prescription.
- The patient/carer must provide a valid prescription for the original medicine that is in shortage.
- The patient/carer must consent to receiving a substitute medicine supplied pursuant to the notice.
- The pharmacist may, in their professional judgement, determine that the patient is not suitable to receive a substitute medicine under the notice e.g. known previous hypersensitivity or severe adverse reaction to excipients.

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