

23<sup>rd</sup> November 2023

Dear Healthcare Professional,

**Shortage of ESTRADERM MX 25 estradiol 25 microgram/24 hours transdermal drug delivery system sachet (AUST R: 67089), and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.**

Due to the shortage of the Australian registered medicine, ESTRADERM MX 25 estradiol 25 microgram/24 hours transdermal drug delivery system sachet (AUST R: 67089), sponsored by Juno Pharmaceuticals Pty Ltd, Reach Pharmaceuticals has arranged the temporary supply of an alternative product called **ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)**, both registered and marketed in Germany.

**ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)** is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until 31<sup>st</sup> March 2024 for the following indication:

*For short-term treatment of signs and symptoms of estrogen deficiency due to the menopause, whether natural or surgically induced.*

*In women with an intact uteri, estrogen should always be opposed by progestogen in an adequate dosage regimen to ensure secretory transformation of the endometrium at regular intervals.*

*Combination HRT should not be used in hysterectomised women because it is not needed in these women and it may increase the risk of breast cancer.*

**Please note: CONTAINS SOYBEAN OIL**

The section 19A approved medicine is **contraindicated** in patients with known hypersensitivity to the active ingredient, soy, peanut or any of the other ingredients listed.

Prior to dispensing and administering, healthcare professionals should determine if this product is suitable for the patient.

Please note the following information regarding differences between **ESTRADERM MX 25 estradiol 25 microgram/24 hours** and **ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)**:

|                          | <b>ESTRADERM MX 25 estradiol 25 microgram/24 hours transdermal drug delivery system sachet (AUST R: 67089)</b>         | <b>ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)</b>  |
|--------------------------|--|---|
| <b>Pack Presentation</b> | <ul style="list-style-type: none"> <li>• Carton of 8 transdermal patches</li> </ul>                                    | <ul style="list-style-type: none"> <li>• Carton of 6 transdermal patches</li> </ul>   |
| <b>Excipients</b>        | <ul style="list-style-type: none"> <li>• Isopropyl palmitate,</li> <li>• acrylate,</li> <li>• methacrylate,</li> </ul> | <ul style="list-style-type: none"> <li>• Matrix: Poly[(2-ethylhexyl)acrylate-co-methylacrylate-co-acrylic acid-co-</li> </ul> |

|                |  |  |
|----------------|--|--|
|                | <ul style="list-style-type: none"> <li>polyethylene terephthalate,</li> <li>ethylene/vinylacetate copolymer and a silicone coating on the inner surface of the protective release liner (discarded before use).</li> </ul> | (2,3-epoxypropyl)methacrylate]<br>(62.2:32.0:5.7:0.03),RRR-alpha-Tocopherol preparation (USP)<br>(contains soybean oil [Ph.Eur.]<br><ul style="list-style-type: none"> <li>Carrier film: Polyethylene terephthalate</li> <li>Protective film: Polyethylene terephthalate, siliconized</li> </ul> |
| <b>Storage</b> | Store below 25°C.  | Do not store above 30°C.   |

The S19A approved German products are identical in active ingredient and strength to the Australian registered product.

Please refer to the Australian Product Information for **ESTRADERM MX 25 estradiol 25 microgram/24 hours transdermal drug delivery system sachet (AUST R: 67089)** (available at <https://www.ebs.tga.gov.au>) when prescribing **ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)**.

Patients should be advised to disregard the German patient leaflet for **ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)** contained within the pack and refer to the English-translated leaflet provided with the medicine for application instructions.

### Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **ESTRAMON estradiol 25 microgram/24 hour transdermal patch (Germany)** should be reported by healthcare professionals and patients to our Medical Information. Reach Pharmaceuticals Medical Information can be contacted by phone on **1800 255 306** or via email at [medical@reach-pharma.com](mailto:medical@reach-pharma.com)

This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

**For sales related enquiries, please contact us on [sales@reach-pharma.com](mailto:sales@reach-pharma.com) or call 0422 429 648.**

We would appreciate if you could distribute this information to those in your organisation who prescribe the product.

**Yours sincerely,**

Reach Pharmaceuticals Pty Ltd