

Date

Dear Healthcare Professional,

**Shortage of ESTRADOT 37.5 estradiol 37.5 microgram transdermal drug delivery system sachet (AUST R: 338057), ESTRADOT 50 estradiol 50 microgram transdermal drug delivery system sachet (AUST R: 338058), ESTRADOT 75 estradiol 75 microgram transdermal drug delivery system sachet (AUST R: 338059), and ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (AUST R: 338060) and alternate supply arrangement under Section 19A of the *Therapeutic Goods Act 1989*.**

**The above Australian registered medicines are in shortage due to manufacturing issues.**

Medsurge has been able to arrange for the supply of **ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany), ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany), ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany) and ESTRAMON estradiol 100 microgram/24 hours transdermal patch** as alternative products on a temporary basis. These products are 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 **Date** for the following indication:

*Short term treatment of symptoms of estrogen deficiency due to the menopause, whether natural or surgically induced.*

*In women with an intact uterus, 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 medicines are 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.**

**ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany), ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany), ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany) and ESTRAMON estradiol 100 microgram/24 hours transdermal patch (Germany)** are identical in active ingredient and strength to the Australian registered products.



A comparison table between the Australian registered **ESTRADOT estradiol transdermal drug delivery system sachet** and **ESTRAMON estradiol transdermal patch (Germany)** is given below:

	<b>ESTRADOT estradiol transdermal drug delivery system sachet</b>	<b>ESTRAMON estradiol transdermal patch (Germany)</b>
<b>Pack Presentation</b>	Carton of 8 transdermal patches	Carton of 6, 18 or 24 transdermal patches
<b>Excipients</b>	Dipropylene glycol, povidone and oleyl alcohol. Proprietary ingredients: Gelva RA-788 acrylic adhesive, BIO-PSA (R) 7-4502 silicone adhesive, Dow BLF 2550 non-removable backing layer film and Scotchpak 1022 removable release liner.	<b>Matrix:</b> Poly[(2-ethylhexyl)acrylate-co-methylacrylate-co-acrylic acid-co-(2,3-epoxypropyl)methacrylate] (62.2:32.0:5.7:0.03), RRR-alpha-Tocopherol preparation (USP) (contains soybean oil [Ph.Eur.]) <b>Carrier film:</b> Polyethylene terephthalate <b>Protective film:</b> Polyethylene terephthalate, siliconized
<b>Storage</b>	Store below 25°C.	Do not store above 30°C.

Please refer to the Australian Product Information for **ESTRADOT 37.5 estradiol 37.5 microgram transdermal drug delivery system sachet (AUST R: 338057)**, **ESTRADOT 50 estradiol 50 microgram transdermal drug delivery system sachet (AUST R: 338058)**, **ESTRADOT 75 estradiol 75 microgram transdermal drug delivery system sachet (AUST R: 338059)**, and **ESTRADOT 100 estradiol 100 microgram transdermal drug delivery system sachet (AUST R: 338060)** available here: [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au) when prescribing **ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany)** and **ESTRAMON estradiol 100 microgram/24 hours transdermal patch (Germany)**.

Patients should be advised to disregard the German patient leaflet for **ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany)** and **ESTRAMON estradiol 100 microgram/24 hours transdermal patch (Germany)** contained within the pack and refer to the English-translated leaflet provided with the medicine for application instructions.

Any adverse events which are experienced with **ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany)** and **ESTRAMON estradiol 100 microgram/24 hours transdermal patch (Germany)** should be reported by healthcare professionals and patients to Medsurge on 1300 788 261 or email [sales@medsurge.com.au](mailto:sales@medsurge.com.au). Alternatively, this information can be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **ESTRAMON estradiol 37.5 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 50 microgram/24 hours transdermal patch (Germany)**, **ESTRAMON estradiol 75 microgram/24 hours transdermal patch (Germany)** and **ESTRAMON estradiol 100 microgram/24 hours transdermal patch (Germany)** should be reported to Medsurge on 1300 788 261 or email [sales@medsurge.com.au](mailto:sales@medsurge.com.au).

**Please forward this information to relevant staff members in your organisation.**

For further information, please contact Medsurge Healthcare on 1300 788 261 or at email [sales@medsurge.com.au](mailto:sales@medsurge.com.au).

Kind regards,

Senior Regulatory Officer

Medsurge Healthcare