PO Box 11183
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New Zealand

4 July 2023

Estradiol Transdermal Patches (Mylan) previously supplied under Section 29

Dear Healthcare Professional,

Viatris Ltd is writing to notify you that our Estradiol Transdermal Patches have been provisionally granted consent registration by Medsafe, in accordance with Section 23 of the NZ Medicines Act. Consequently, this product will no longer be supplied under Section 29, thereby eliminating the reporting obligations of the supply to the Director-General of Health as of 05th of July 2023.

Background

The products were intended for the US market and have been supplied intermittently under Section 29 since 2020. The packaging contains the US Prescribing Information as a pack insert instead of the NZ Data Sheet.

Healthcare Professionals are advised to refer to the approved NZ Data Sheet for information on the product.

Differences highlighted between the NZ Data Sheet (DS) and US Prescribing Information (PI)

New Zealand Data Sheet	US Prescribing Information
No Boxed Warning	**Boxed Warning in the US PI** Some of the information in the NZ DS under section *"4.4 Special warnings and precautions for use"* is included as a boxed warning in the US PI: *"WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, PROBABLE DEMENTIA, and BREAST CANCER See full prescribing information for complete boxed warning."*
Dosage Forms and Strengths No mention of 0.0375 mg per day formulation. (This strength is not registered in New Zealand)	**Dosage Forms and Strengths** The US PI refers to the 0.0375 mg per day formulation.
The indications sections in both the NZ DS and US PI are closely aligned.	
Therapeutic Indications *"In women with an intact uterus, oestrogens should always be supplemented by administration of a progestogen"*	**Therapeutic Indications** US PI includes additional *"Limitations of Use."* See below reproduces the indications sections.
Oestrogen replacement therapy for the treatment of the symptoms of natural or surgically induced menopause Prevention of postmenopausal osteoporosis (see Dosage and Administration and Warnings and Precautions). In women with an intact uterus, oestrogens should always be supplemented by administration of a progestogen.	Treatment of moderate to severe vasomotor symptoms due to menopause Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause Limitations of Use: When prescribing solely for the treatment of moderate to severe vaginal atrophy, first consider the use of topical vaginal products. Treatment of hypoestrogenism due to hypogonadism, castration, or primary ovarian failure

	Prevention of postmenopausal osteoporosis Limitations of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of non-estrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.
Dose and Method of Administration Treatment should be initiated with the lowest dose. Patches are administered as continuous therapy (uninterrupted application twice weekly).	**Dose and Method of Administration** US PI states to start therapy with 0.0375 mg per day for symptoms of menopause or vulvar and vaginal atrophy due to menopause. Continuous therapy is in women who do not have an intact uterus, whereas women with an intact uterus are to be administered therapy on a cyclic schedule (for example, 3 weeks on followed by 1 week off).
Method of application The instructions in both leaflets are closely aligned.	
Contraindications Additional contraindications in the NZ DS include porphyria, known/suspected pregnancy, and breastfeeding.	**Contraindications** Closely aligned to NZ DS.

PLEASE REVIEW THE CURRENT DATA SHEET BEFORE PRESCRIBING.

The ESTRADIOL TRANSDERMAL PATCHES (MYLAN) Data Sheet and Consumer Medicine Information can be found at: https://www.medsafe.govt.nz/Medicines/infoSearch.asp

Adverse Event Reporting

Please report any suspected adverse events via email to **medinfo_anz@viatris.com.** Alternatively, suspected adverse events may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin online at https://nzphvc.otago.ac.nz/ reporting or by email to **carmnz@otago.ac.nz.**

Medical Enquiries

Please direct any medical enquiries to Viatris or report any suspected adverse drug reactions to Viatris via telephone on 0800 168 169 or by email at **medinfo_anz@viatris.com.**

Yours sincerely,

Manar Al-Murrani

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Medical Affairs Specialist

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