PO Box 11183
Ellerslie
Auckland 1542
New Zealand

22 May 2025

Estradiol Transdermal Patches (Mylan)

Dear Healthcare Professional,

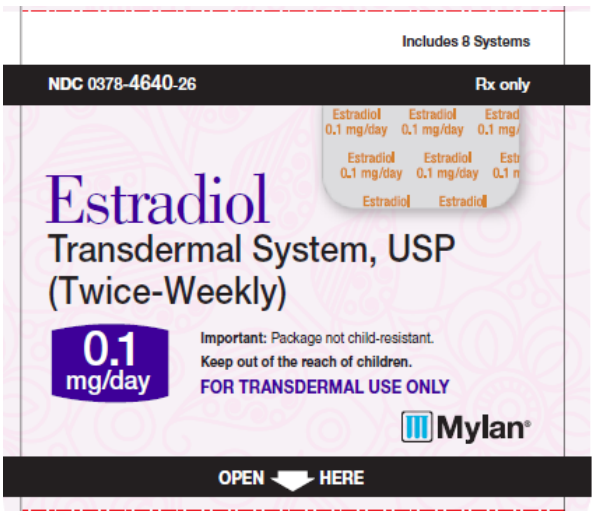
Viatris Ltd is writing to notify you that our Estradiol Transdermal Patches have been granted full consent by Medsafe on 22 May 2025, in accordance with Section 20 of the New Zealand Medicines Act. The product has been previously supplied under Section 23 of the New Zealand Medicines Act (Provisional Consent).

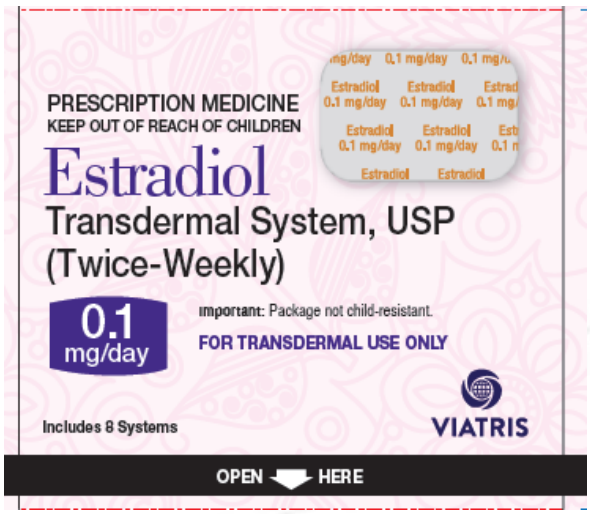
Background

Supply to the New Zealand market up to now has been with the existing packaging as is currently registered/supplied in the United States of America. The US packaging contains the US Prescribing Information as a pack insert instead of the NZ Data Sheet. A summary of the differences between the New Zealand Data Sheet and the US prescribing information is presented below.

As part of the approval under section 20 of the New Zealand Medicines Act, New Zealand-specific packaging has been approved by Medsafe. Viatris Ltd is currently working with the supplier of Estradiol Transdermal Patches to transition to New Zealand-specific packs as quickly as possible. The New Zealand-specific packs will only contain information relevant to New Zealand Health Care Professionals and Patients.

The US packs will continue to be supplied in the short term. The only difference between the US packs and the NZ packs is the labelling. The New Zealand-specific packs will include the Viatris logo rather than the Mylan logo on the cartons.





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 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. Estradiol Transdermal Patches should be applied every 3 to 4 days (i.e. twice weekly). Patches are administered as continuous therapy (uninterrupted application twice weekly).	**Dose and Method of Administration** US PI states ""Generally, when estrogen is prescribed for a postmenopausal woman with a uterus, consider addition of a progestogen to reduce the risk of endometrial cancer." Start therapy with 0.0375 mg per day for moderate to severe vasomotor symptoms due to 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, Breastfeeding.	**Contraindications** Closely aligned to NZ DS but include anaphylaxis and angioedema to estradiol product, and lists specific thrombophilic disorders i.e., protein C/S, antithrombin deficiency or other.

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://pophealth.my.site.com/carmreportnz/s/ 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
Manar Al-Murrani
Medical Affairs Specialist