

10 August 2023

Estradiol Transdermal Patches (Mylan) – Alternative Registered Carton

Dear Healthcare Professional,







We are writing to provide you with an important update regarding Viatriis Ltd's Estradiol Transdermal Patches (provisional consent). Following our previous communication in July 2023, we want to inform you that our Estradiol Transdermal Patches (Mylan) will be available in an alternative registered carton alongside the existing one.



Background

In order to ensure a consistent supply of Estradiol Transdermal patches, we have introduced an alternative registered carton for the product. This change involves an update in the carton presentation and the leaflet. It is important to note that both the existing registered carton and the alternative carton may coexist in the market. The packaging contains 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.

Summary of the Updates

Existing Registered Carton	Alternative Registered Carton
	
	
	

Existing Registered Carton	Alternative Registered Carton
	
<p>Indication as set out in the enclosed leaflet as per the USA Prescribing Information:</p> <p>1.1 Treatment of Moderate to Severe Vasomotor Symptoms Due to Menopause.</p> <p>1.2 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 symptoms of vulvar and vaginal atrophy, first consider the use of topical vaginal products.</p> <p>1.3 Treatment of Hypoestrogenism Due to Hypogonadism, Castration, or Primary Ovarian Failure.</p> <p>1.4 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.</p>	<p>Indication as set out in the enclosed leaflet as per the USA Prescribing Information:</p> <p>1.1 Treatment of Moderate to Severe Vasomotor Symptoms Due to Menopause.</p> <p>1.2 Prevention of Postmenopausal Osteoporosis Limitations of Use: When prescribing solely for the prevention of postmenopausal osteoporosis, first consider the use of nonestrogen medications. Consider estrogen therapy only for women at significant risk of osteoporosis.</p>

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> A summary of the differences between the NZ Data Sheet and the US Prescribing Information is outlined in our previous communication, dated 4 July 2023, and is available from: <https://www.medsafe.govt.nz/safety/DHCPletters/Estradiol4July2023.pdf>

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

Manar Al-Murrani
Medical Affairs Specialist

This information is provided to address your specific enquiry and is for your personal reference only. Please note that Viatris only recommends the use of its products in accordance with the approved Product Information.

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