WELLMED.NZ LIMITED
Level 1, 50 Customhouse Quay
Wellington
New Zealand

25 September 2024

Lyllana® (estradiol) Transdermal Patches
0.025 mg/day, 0.05 mg/day, 0.075 mg/day, 0.1 mg/day estradiol

Dear Healthcare Professional,

Wellmed.NZ Ltd is writing to notify you that our estradiol transdermal patches (LYLLANA) on 25 September 2024 have been granted provisional consent by Medsafe, in accordance with Section 23 of the NZ Medicines Act.

Background

The product is to be packed in the US packaging with a labelling exemption from Medsafe.

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/Pack insert
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."
Therapeutic indications • Oestrogen (also known as estrogen) replacement therapy for the treatment of the symptoms of natural or surgically induced menopause. • Prevention of postmenopausal osteoporosis (see '*4.2 Dose and method of administration*' and '*4.4 Special warnings and precautions for use'*) In women with an intact uterus, oestrogens should always be supplemented by administration of a progestogen.	**Therapeutic indications** 1.1 Treatment of Moderate to Severe Vasomotor Symptoms Due to Menopause 1.2 Prevention of Postmenopausal Osteoporosis Limitation 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 at the lowest dose. Woman should be closely monitored.	**Dose and method of administration** US PI states to start therapy with 0.0375 mg per day for treatment of moderate to severe vasomotor symptoms due to menopause and to attempt to taper or discontinue at 3 to 6 month intervals.
Contraindications There are additional contraindications: porphyria, known or suspected pregnancy, breastfeeding.	

PLEASE REVIEW THE CURRENT DATA SHEET BEFORE PRESCRIBING.

The LYLLANA 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 info@wellmed.nz. Alternatively, suspected adverse events may be reported to the Centre for Adverse Reactions Monitoring (CARM) online at https://pophealth.my.site.com/carmreportnz/s/ .

Medical Enquiries

Please direct any medical enquiries to Wellmed.NZ via telephone on 0800 488 866 or by email at info@wellmed.nz.

Yours sincerely,

Nicholas Leach
CEO WellMed.NZ Limited