Public Summary

Summary for ARTG Entry: 67090 ESTRADERM MX 100 estradiol 100 microgram/24 hours (3mg) transdermal drug delivery system sachet

ARTG entry for	Medicine Registered
Sponsor	Juno Pharmaceuticals Pty Ltd
Postal Address	Level 2 6 Bond Street, South Yarra, VIC, 3141 Australia
ARTG Start Date	15/02/1999
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. ESTRADERM MX 100 estradiol 100 microgram/24 hours(3mg) transdermal drug delivery system sachet

Product Type Single Medicine Product **Effective date** 12/01/2018

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Menopausal symptoms: Short-term treatment of signs and symptoms of oestrogen deficiency due to menopause, whether natural or surgically induced. In women with an intact uterus, oestrogen should always be opposed by progestogen in an adequate dosage regimen to ensure secretory transformation of the endometrium at regular intervals (Refer to CLINICAL TRIALS and DOSAGE AND ADMINISTRATION). Prevention of post-menopausal bone mineral density loss: Estraderm MX 50, 75 and 100 may be used for prevention of post-menopausal bone mineral density loss in women with an increased risk of future osteoporotic fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of bone mineral density loss. When prescribed solely for the prevention of postmenopausal bone mineral density loss, therapy should only be prescribed for women who are at high risk of future fracture and who are intolerant of, or contraindicated for, non-oestrogen products approved for prevention of bone mineral density loss. Lifestyle modifications and the risk-benefit profile of Estraderm MX should be taken into careful consideration and discussed with the patient to allow the patient to make an informed decision prior to prescribing(See PRECAUTIONS and DOSAGE AND ADMINISTRATION). Combination HRT should not be used in hysterectomised women because it is not needed in these women and it may increase risk of breast cancer.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
2 sachets	(S4) Prescription Only Medicine
8 sachets	(S4) Prescription Only Medicine

Components

1. ESTRADERM MX 100 estradiol 100 microgram/24 hours (3 mg) transdermal drug delivery system sachet

Dosage Form	Drug delivery system, transdermal
Route of Administration	Transdermal
Visual Identification	Thin, flat, colourless, translucent multilaminate sheet; 70.11mm in diameter; square with rounded corners and impressed with "CG GTG".

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Active Ingredients	
estradiol	**3 mg**

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