



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 67089 ESTRADERM MX 25 estradiol 25 microgram/24 hours (0.75mg) 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 25 estradiol 25 microgram/24 hours (0.75mg) transdermal drug delivery system sachet

Product Type	Single Medicine Product	Effective date	12/01/2018
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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). 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
8 sachets	(S4) Prescription Only Medicine
2 sachets	(S4) Prescription Only Medicine

Components

1. ESTRADERM MX 25 estradiol 25 microgram/24 hours (0.75 mg) transdermal drug delivery system sachet

Dosage Form Drug delivery system, transdermal

Route of Administration Transdermal

Visual Identification Thin, flat, colourless, translucent multilaminate sheet; 35.13mm in diameter; square with rounded corners and impressed with "CG GRG".

Active Ingredients

estradiol .75 mg

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