Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	325361	Estrogel Pro
ARTG entry for	Medicine Listed	
Sponsor	Besins Healthcare Australia Pty Ltd	
Postal Address	Level 16 Tower 2 Darling Park, 201 Sussex Street, Sydney, NSW, 2000 Australia	
ARTG Start Date	23/10/2019	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Estrogel Pro

Product Type Medicine Kit **Effective Date** 14/01/2020

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Indications

Estrogel ®
Hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women
Prometrium® 100 mg
Hormone replacement therapy - adjunctive use with oestrogen in postmenopausal women with an intact uterus

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

For external use only.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . PROMETRIUM 100 progesterone 100 mg soft capsule blister pack (ARTG: 232818)

2 . ESTROGEL estradiol (as hemihydrate) 0.06% w/w gel pump pack (ARTG: 301620)

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