

Public Summary

Summary for ARTG Entry: 42933 PROVERA Medroxyprogesterone acetate 5mg tablet blister pack (New Formula)

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
Australia
ARTG Start Date 7/01/1993
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. PROVERA Medroxyprogesterone acetate 5mg tablet**

Product Type Single Medicine Product **Effective date** 9/03/2017

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

1. Carcinoma: Palliative treatment of recurrent and/or metastatic breast or renal cell cancer and of inoperable recurrent or metastatic endometrial carcinoma. 2. Endometriosis: For use in the treatment of visually proven (laparoscopy) endometriosis where the required end-point of treatment is pregnancy, or for the control of symptoms when surgery is contraindicated or has been unsuccessful. 3. Secondary Amenorrhoea proven not due to pregnancy: In amenorrhoea associated with a poorly developed proliferative endometrium, conventional oestrogen therapy may be employed in conjunction with medroxyprogesterone acetate. 4. Abnormal Uterine Bleeding: In the absence of organic pathology. 5. Adjunct to Oestrogen Therapy: Combination hormone replacement therapy should only be used in non-hysterectomised women.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/Al	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information**Pack Size**

28 and 56 tablets

Poison Schedule

(S4) Prescription Only Medicine

Components**1. Medicine Component****Dosage Form**

Tablet, uncoated

Route of Administration

Oral

Visual Identification

Pale blue, round tablets. One surface is engraved with the logo "286" on both sides of a break-score. The other surface is engraved with the logo "U"

Active Ingredients

Medroxyprogesterone acetate 5 mg