Public Summary

Summary for ARTG Entry:	401610	DEPO-PROVERA medroxyprogesterone acetate 150 mg/1 mL suspension for injection pre-filled syringe

ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	Level 17 151 Clarence Street, Sydney, NSW, 2000 Australia
ARTG Start Date	3/05/2023
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 . DEPO-PROVERA medroxyprogesterone acetate 150 mg/1 mL suspension for injection pre-filled syringe

Product Type	Single Medicine Product	**Effective Date**	29/11/2023

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

Carcinoma: Palliative treatment of recurrent and/or metastatic breast or renal cell cancer and of inoperable recurrent or metastatic endometrial carcinoma. 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 contra- indicated or has been unsuccessful. Contraception (ovulation suppression): For long-term prevention of pregnancy in women when administered at 3-month intervals. Since loss of bone mineral density (BMD) may occur in pre-menopausal women who use DEPO-PROVERA long-term (greater than 2 years), women should be assessed, before starting treatment for contraception or endometriosis, regarding the risk of osteoporosis. Women under the age of 18 years may be at risk of failing to achieve their predicted peak bone mineral density (See WARNINGS). The 50 mg/1mL vial is not approved for the indication of contraception (ovulation suppression). The injection, DEPO-PROVERA 150 mg/1mL, should be used for contraception.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass Type I Clear	60 Months	Store below 30 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Refrigerate Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1mL X 1	(S4) Prescription Only Medicine

Components

1 . DEPO-PROVERA medroxyprogesterone acetate 150 mg/1 mL suspension for injection pre-filled syringe

Dosage Form	Injection, suspension

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Route of Administration	Intramuscular
Visual Identification	White suspension

Active Ingredients	
medroxyprogesterone acetate	**150 mg/mL**

Other Ingredients (Excipients)
macrogol 3350
methyl hydroxybenzoate
polysorbate 80
propyl hydroxybenzoate
sodium chloride
water for injections

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