



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

**Summary for ARTG Entry:** 167889 SAYANA medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection syringe

**ARTG entry for** Medicine Registered  
**Sponsor** Pfizer Australia Pty Ltd  
**Postal Address** 38-42 Wharf Road, WEST RYDE, NSW, 2114  
Australia  
**ARTG Start Date** 14/07/2011  
**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. SAYANA medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection syringe

| Product Type | Single Medicine Product | Effective date | 19/01/2018 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

### 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

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 SAYANA 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 PRECAUTIONS).

### 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    | 3 Years   | Store below 25 degrees Celsius | Not recorded | Do not Freeze |

### Pack Size/Poison information

#### Pack Size

1 x pre-filled syringe

#### Poison Schedule

(S4) Prescription Only Medicine

#### Components

##### 1. SAYANA medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection syringe

|                                |                                                                   |
|--------------------------------|-------------------------------------------------------------------|
| <b>Dosage Form</b>             | Suspension                                                        |
| <b>Route of Administration</b> | Subcutaneous                                                      |
| <b>Visual Identification</b>   | white to off-white homogeneous suspension in a pre-filled syringe |
| <b>Active Ingredients</b>      |                                                                   |
| Medroxyprogesterone acetate    | 104 mg                                                            |



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Public Summary