Summary for ARTG Entry: 328120
OVALEAP 450IU/0.75mL follitropin alfa (rch) solution for injection, cartridge

ARTG entry for
Medicine Registered

Sponsor
Theramex Australia Pty Ltd

Postal Address
Level 22 60 Margaret Street, Sydney, NSW, 2000
Australia

ARTG Start Date
10/03/2021

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. OVALEAP 450IU/0.75mL follitropin alfa (rch) solution for injection, cartridge

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. The treatment of anovulatory infertility in women who have been unresponsive to clomiphene citrate or where clomiphene citrate is contraindicated.
2. For controlled ovarian hyperstimulation in women undergoing assisted reproductive technologies.
3. OVALEAP is indicated with concomitant human chorionic gonadotrophin (hCG) therapy for the stimulation of spermatogenesis in gonadotrophin-deficient men in whom hCG alone is ineffective.

Warnings
See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type
Cartridge

Material
Glass Type I Clear

Life Time
36 Months

Temperature
Store at 2 to 8 degrees Celsius

Closure
Neither child resistant closure nor restricted flow insert

Conditions
Do not Freeze Refrigerate

Pack Size/Poison information

Pack Size
1

Poison Schedule
(S4) Prescription Only Medicine

Components
1. OVALEAP 450IU/0.75mL follitropin alfa (rch) solution for injection, cartridge

Dosage Form
Injection, solution

Route of Administration
Subcutaneous

Visual Identification
Clear and colourless liquid in a cartridge consisting of a glass carpule with a grey rubber stopper and a cartridge seal

Active Ingredients

Follitropin alfa
450 IU

Other Ingredients (Excipients)
benzalkonium chloride
benzyl alcohol
mannitol
methionine
monobasic sodium phosphate dihydrate
polysorbate 20
sodium hydroxide
water for injections