Public Summary

Summary for ARTG Entry:	374374 CIPTUNEC adalimumab 80 mg/0.8 mL solution for subcutaneous injection pre-filled syringe
ARTG entry for	Medicine Registered
Sponsor	Cipla Australia Pty Ltd
Postal Address	Level 1 / 132-136 Albert Road, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	6/09/2022
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 . CIPTUNEC adalimumab 80 mg/0.8 mL solution for subcutaneous 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

Rheumatoid arthritis,Ciptunec is indicated for reducing signs and symptoms, as well as inhibiting the progression of structural damage in adult patients with moderate to severely active rheumatoid arthritis. This includes the treatment of patients with recently diagnosed moderate to severely active disease who have not received methotrexate.
Ciptunec can be used alone or in combination with methotrexate.,Juvenile idiopathic arthritis,Polyarticular juvenile idiopathic arthritis,Ciptunec in combination with methotrexate is indicated for reducing the signs and symptoms of
moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and
older weighing greater than or equal to 30 kg who have had an inadequate response to one or more disease modifying antirheumatic drugs (DMARDs).
Ciptunec can be given as monotherapy in case of intolerance to
methotrexate or when continued treatment with methotrexate is inappropriate.,Enthesitis-related arthritis,Ciptunec is indicated for the treatment of enthesitis-related arthritis in children, who have had an
inadequate response to, or who are intolerant to, conventional therapy.,Psoriatic arthritis
Ciptunec is indicated for the treatment of signs and symptoms, as well as inhibiting the progression of
structural damage, of moderate to severely active psoriatic arthritis in adult patients where response
to previous DMARDs has been inadequate.,Ankylosing spondylitis,Ciptunec is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.,Crohn's disease in adults and children (greater than or equal to 6 years; weighing greater than or equal to 40 kg),Ciptunec is indicated for the treatment of moderate to severe Crohn's disease, to reduce the signs
and symptoms of the disease and to induce and maintain clinical remission in patients;
? who have had an inadequate response to conventional therapies or,
? who have lost response to or are intolerant to infliximab,Ulcerative colitis,Ciptunec is indicated for the treatment of moderate to severe ulcerative colitis in adult patients who
have had an inadequate response to conventional therapy or who are intolerant to or have medical
contraindications for such therapies. Patients should show a clinical response within 8 weeks of
treatment to continue treatment beyond that time (see section 5.1 Pharmacodynamic properties -
clinical trials).,Psoriasis in adults and children,Ciptunec is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.,Ciptunec is indicated for the treatment of severe chronic plaque psoriasis in children and adolescent
patients from 4 years of age weighing greater than or equal to 40 kg who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapy.,Hidradenitis suppurativa in adults and adolescents (from 12 years of age),Ciptunec is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in patients with an inadequate response to conventional systemic hidradenitis suppurativa therapy.,Uveitis,Ciptunec is indicated for the treatment of non-infectious intermediate, posterior and pan-uveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid sparing, or in whom corticosteroid treatment is inappropriate.

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	24 Months	Store at 2 to 8 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1 pre-filled syringe	(S4) Prescription Only Medicine

Components

1 . CIPTUNEC adalimumab 80 mg/0.8 mL solution for subcutaneous injection pre-filled syringe

Dosage Form	Injection, solution
Route of Administration	Subcutaneous
Visual Identification	AVT02 is a clear, colorless, sterile, preservative-free solution for subcutaneous injection

Active Ingredients

Adalimumab	**80 mg**

Other Ingredients (Excipients)

polysorbate 80
sodium chloride
sucrose
water for injections

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