

CinnoRA[®]

Adalimumab



Description

CinnoRA[®] contains Adalimumab as an active substance.



Dosage Forms

Sterile Pre-filled Syringe or Physioject containing 40 mg/0.8 mL for subcutaneous injection



Indications

Adalimumab is indicated for the treatment of:

Rheumatology:

- **Juvenile Idiopathic Arthritis:** Treatment (to reduce signs/symptoms) of active polyarticular juvenile idiopathic arthritis (moderate to severe) in pediatric patients ≥ 2 years of age; may be used alone or in combination with methotrexate
- **Rheumatoid Arthritis:** Treatment (to reduce signs/symptoms, induce major clinical response, inhibit progression of structural damage, and improve physical function) of active rheumatoid arthritis (moderate to severe) in adults; may be used alone or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)
- **Spondyloarthritis**
 - Axial Spondyloarthritis (e.g., Ankylosing Spondylitis):** Treatment (to reduce signs/symptoms) of active ankylosing spondylitis in adults. May also be used off-label for nonradiographic axial spondyloarthritis
 - Psoriatic Arthritis:** Treatment (to reduce signs/symptoms, inhibit progression of structural damage, and improve physical function) of psoriatic arthritis (a form of peripheral spondyloarthritis) in adults; may be used alone or in combination with nonbiologic DMARDs. May also be used off-label for nonpsoriatic peripheral spondyloarthritis

Dermatology:

- **Hidradenitis Suppurativa, moderate to severe, refractory:** Treatment in adults and pediatric patients ≥ 12 years of age

CinnoRA[®]

Adalimumab

- **Plaque Psoriasis, moderate to severe:** Treatment of chronic plaque psoriasis (moderate to severe) in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are less appropriate

Gastroenterology:

- **Crohn's disease, moderately to severely active:** Treatment in adults and pediatric patients ≥ 6 years of age
- **Ulcerative Colitis, moderate to severe, induction and maintenance of remission:** Treatment of moderately to severely active ulcerative colitis in adults and pediatric patients ≥ 5 years of age

Treatment of noninfectious intermediate, posterior, and panuveitis in adults and pediatric patients ≥ 2 years of age

Dosing: Adult

The dosing regimens are specified for the SUBQ formulation.

Rheumatology:

- **Rheumatoid Arthritis**
Initial: 40 mg every other week; for select patients with an inadequate response, may increase dose to 40 mg every week or 80 mg every other week.
- **Axial Spondyloarthritis, including Ankylosing Spondylitis, Psoriatic Arthritis**
40 mg every other week

Dermatology:

- **Hidradenitis Suppurativa, moderate to severe, refractory**
Initial: 160 mg (given over 1 or 2 days), then 80 mg 2 weeks later (day 15).
Maintenance: 40 mg every week beginning day 29 or 80 mg every other week beginning day 29
- **Plaque Psoriasis, moderate to severe**
Initial: 80 mg as a single dose.
Maintenance: 40 mg every other week beginning 1 week after initial dose

Gastroenterology:

- **Crohn's disease, moderately to severely active**

CinnoRA[®]

Adalimumab

Initial: 160 mg (given over 1 or 2 days), followed by 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every other week beginning day 29

- **Ulcerative Colitis, moderate to severe, induction and maintenance of remission**

Induction: 160 mg (given over 1 or 2 days), then 80 mg 2 weeks later (day 15).

Maintenance: 40 mg every other week beginning day 29

Uveitis, noninfectious

Initial: 80 mg as a single dose.

Maintenance: 40 mg every other week beginning 1 week after initial dose. For patients who do not achieve control of inflammation after 4 months, consider increasing the dose to 40 mg every week

Dosing: Pediatric

The dosing regimens are specified for the SUBQ formulation.

Rheumatology:

- **Juvenile Idiopathic Arthritis (JIA) Children ≥ 2 years and Adolescents:**

10 kg to <15 kg: 10 mg every other week

15 to <30 kg: 20 mg every other week

≥ 30 kg: 40 mg every other week

Dermatology:

- **Hidradenitis Suppurativa Children ≥ 12 years and Adolescents:**

30 to <60 kg:

Initial: 80 mg on day 1.

Maintenance (beginning day 8): 40 mg every other week

≥ 60 kg:

Initial: 160 mg (administered as a full dose on day 1 or split doses and administered over 2 consecutive days), then 80 mg 2 weeks later (day 15).

Maintenance (beginning day 29): 40 mg weekly or 80 mg every other week.

Gastroenterology:

- **Crohn's disease, moderate to severe Children ≥ 6 years and Adolescents:**

17 kg to <40 kg:

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Adalimumab

Initial: 80 mg on day 1, then 40 mg administered 2 weeks later (day 15)

Maintenance (beginning day 29): 20 mg every other week. Patients who continue to experience flares after 12 weeks of therapy may benefit from weekly dosing

≥40 kg:

Initial: 160 mg (administered on day 1 or split and administered over 2 consecutive days), then 80 mg administered 2 weeks later (day 15)

Maintenance (beginning day 29): 40 mg every other week

- **Ulcerative Colitis, moderate to severe Children ≥5 years and Adolescents:**

20 to <40 kg:

Initial: 80 mg on day 1, then 40 mg administered weekly for 2 weeks (a dose on day 8 and day 15).

Maintenance (beginning day 29): 40 mg every other week or 20 mg every week.

≥40 kg:

Initial: 160 mg on day 1 (administered as a full dose on day 1 or split doses and administered over 2 consecutive days), then 80 mg administered weekly for 2 weeks (a dose on day 8 and day 15).

Maintenance (beginning day 29): 80 mg every other week or 40 mg every week

Treatment of noninfectious intermediate, posterior, and panuveitis in adolescents and pediatric patients ≥2 years of age

10 kg to <15 kg: 10 mg every other week.

15 to <30 kg: 20 mg every other week.

≥30 kg: 40 mg every other week



Administration

Administration: Adult, Pediatric

Administer subcutaneously in the thigh or lower abdomen, avoiding areas within 2 inches of the navel. Rotate injection sites. If multiple injections are needed for one dose, give each injection at a separate site at least 1 inch apart. Do not inject into skin that is red, tender, bruised, hard, or has scars, stretch marks, or psoriasis plaques. Allow the product to reach room temperature for about 15 to 30 minutes before use; do not remove the cap or cover during this time. Do not use if the solution is discolored or

CinnoRA[®]

Adalimumab

contains particulate matter. Pre-filled pens and syringes are available for self-administration; the full amount of the syringe should be injected. Citrate-free formulations may cause less injection pain. Needle caps or covers may contain latex.



Adverse Reactions

>10%

Dermatologic: Skin rash (12%)

Hematologic & oncologic: Positive antinuclear antibody (ANA) titer (12%)

Immunologic: Antibody development (3% to 26%)

Infections (more than 10%)

Local: Injection-site reaction (5% to 20%; including bleeding at injection site, erythema at injection site, injection-site pruritus, pain at injection site, swelling at injection site)

Nervous system: Headache (12%)

Neuromuscular & skeletal: Increased creatine phosphokinase in blood specimen (children, adolescents: 15%)

Respiratory: Sinusitis (11%), upper respiratory tract infection (17%)



Reproductive Considerations

The American Academy of Dermatology considers tumor necrosis factor (TNF) blocking agents for the treatment of psoriasis to be compatible for use in patients planning to father a child. Patients with psoriasis planning to become pregnant may continue treatment with adalimumab. Patients with well-controlled psoriasis who wish to avoid fetal exposure can consider discontinuing adalimumab 10 weeks prior to attempting to become pregnant.

Biologics, such as adalimumab, may be continued in patients with inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis) planning to become pregnant.



Pregnancy Considerations

Adalimumab crosses the placenta, especially in later pregnancy, and may remain in the newborn's

CinnoRA[®]

Adalimumab

blood for months after birth. Available data do not show an increased risk of major birth defects, but infants exposed in the third trimester may be considered temporarily immunosuppressed.

If needed during pregnancy, treatment should be individualized, and live vaccines should be avoided in the infant for the first 6 months after late pregnancy exposure.



Breastfeeding Considerations

Adalimumab is present in breast milk in very small amounts, usually at low levels. No increased risk of infection has been observed in breastfed infants exposed to adalimumab through maternal use. It is generally considered compatible with breastfeeding, but the decision should balance infant exposure, breastfeeding benefits, and the mother's need for treatment.



Contraindications

Known hypersensitivity to adalimumab or any component of the formulation; severe infection (e.g., sepsis, tuberculosis, opportunistic infection); moderate-to-severe heart failure (NYHA class III/IV)



Monitoring Parameters

Before therapy

- Screen for malignancy (especially skin cancer), heart failure, neurologic disease, lymphadenopathy and current/latent infection
- Ensure vaccinations are up to date; avoid live vaccines within 4 weeks of starting therapy
- Obtain baseline labs: CBC, CMP, pregnancy test, CRP, hepatitis B serology, hepatitis C antibody, HIV, and TB testing; get a chest X-ray if TB testing is positive

During therapy

- Monitor for malignancy, infections, heart failure, neurologic symptoms, hypersensitivity, lupus-like syndrome, and injection-site reactions
- Check CBC and LFTs at 4 and 12 weeks, then every 3–6 months
- Follow disease activity and consider anti-drug antibody testing or therapeutic drug monitoring if response is lost

CinnoRA[®]

Adalimumab

After therapy

- Continue periodic monitoring for active hepatitis B in HBV carriers



Storage/Stability

Store at 2°C to 8°C in the original container to protect from light; do not freeze.



Reference

Adalimumab Drug Information, UpToDate [July 2026]

CinnoRA[®]

Manufactured by CinnaGen, the first and only Iranian pharmaceutical company with European Union approval