Advanced Therapy In Rheumatology

Presented by:
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MSL
December 2025

Rheumatology

Medications

PART
01

A brief of CinnoRA®

Generic Name:
Adalimumab

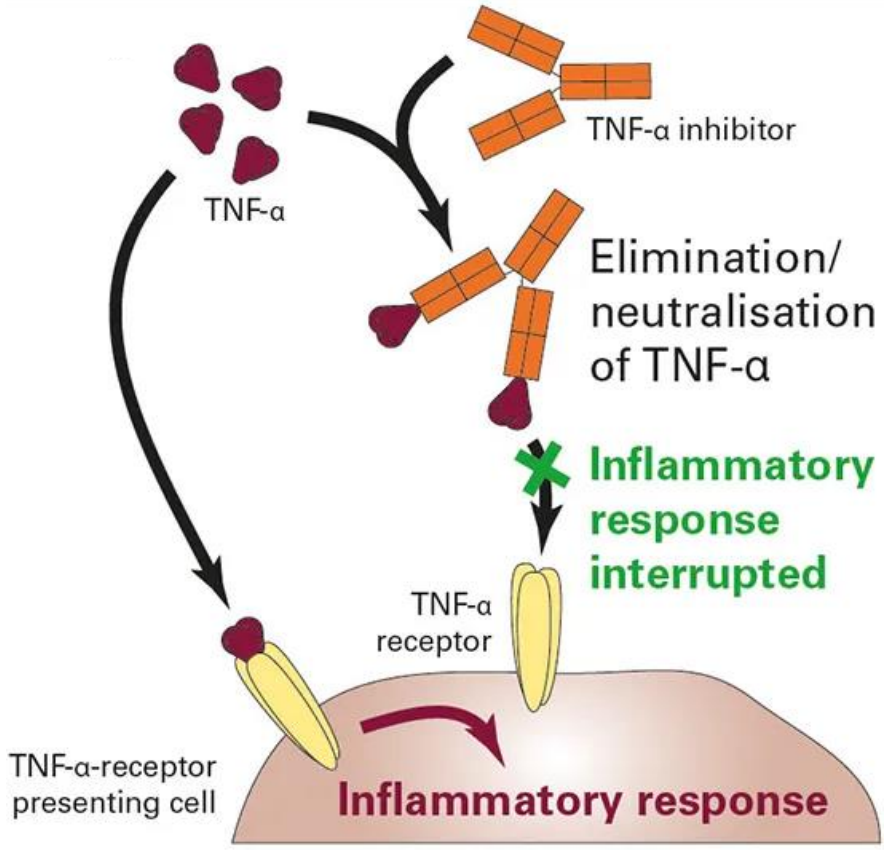
Dosage Form:
Physioject,PFS
40 mg/ 0.8 ml

Adalimumab

CinnoRA®
Adalimumab

Mechanism of action

Adalimumab is a recombinant monoclonal antibody that binds to human tumor necrosis factor-alpha (TNF-alpha), thereby interfering with binding to TNFα receptor sites and subsequent cytokine-driven inflammatory processes. It reduces epidermal thickness and inflammatory cell infiltration in plaque psoriasis.



Monitoring Parameters

CinnoRA® Adalimumab

- ✓ CBC with differential (baseline)
- ✓ Metabolic panel (baseline)
- ✓ TB screening (prior to initiating & during therapy)
- ✓ HBV/HCV screening prior to initiating (all patients)
- ✓ HIV screening in high risk patients (baseline)
- ✓ Signs/symptoms of heart failure/Infection/ lupus-like Syndrome/malignancy

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✓ Monitor improvement of symptoms and physical function assessments.

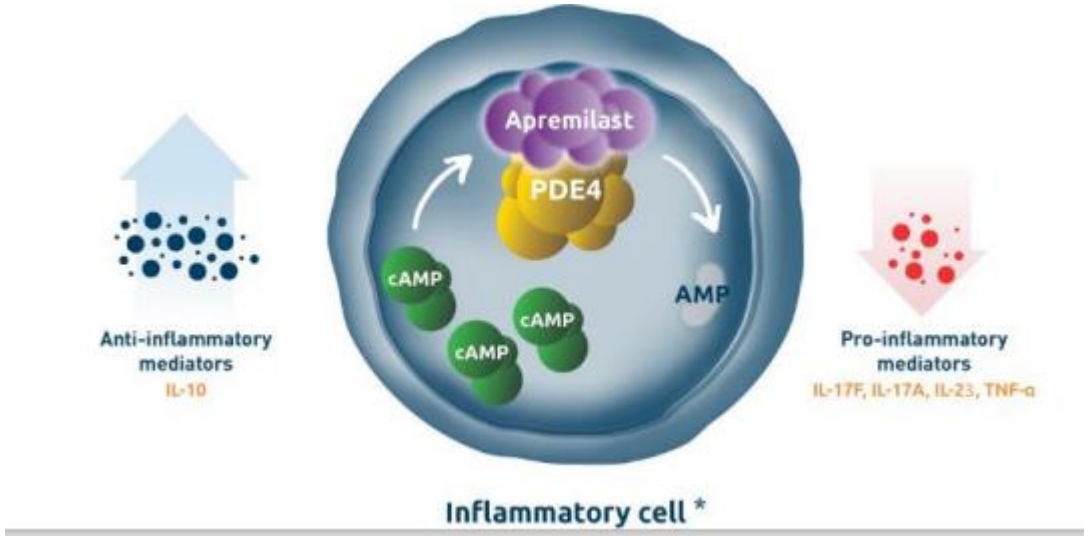
PART
02

A brief of Premilatic®

Apremilast

Mechanism of action

Apremilast inhibits phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) which results in increased intracellular cAMP levels and regulation of numerous inflammatory mediators (eg, decreased expression of nitric oxide synthase, TNF-α, and IL-23, as well as increased IL-10).



Apremilast

Use: Labeled Indications

1. **Psoriasis**: Treatment of adults with plaque psoriasis who are candidates for phototherapy or systemic therapy. Treatment of pediatric patients ≥6 years of age and ≥20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

2. **Psoriatic arthritis:** Treatment of patients with active psoriatic arthritis.

3. **Behçet disease:** Treatment of oral ulcers associated with Behçet disease.

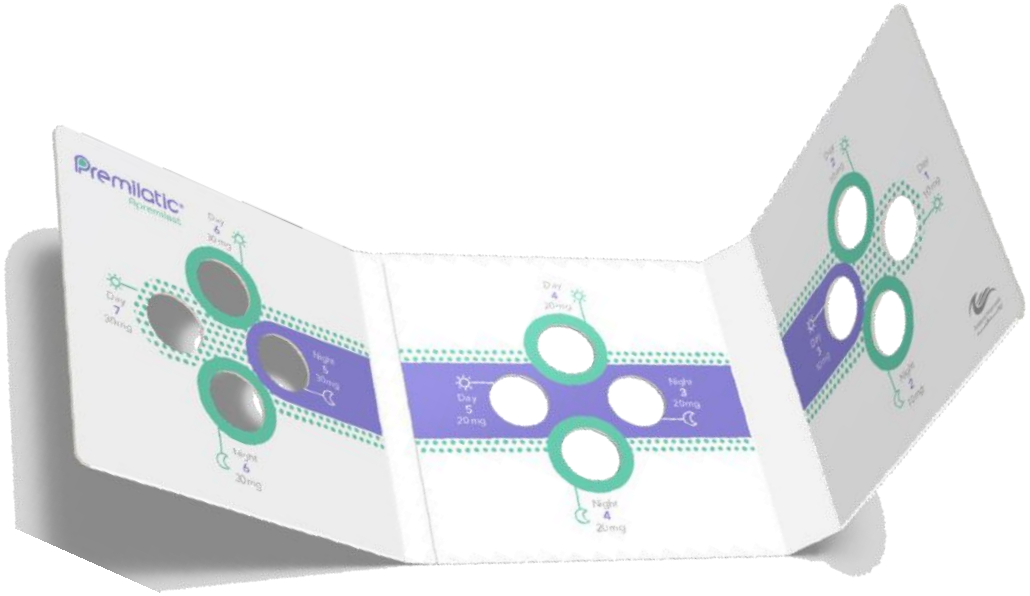
Premilatic Packaging

Premilatic®
Apremilast

Starter Pack:

Contains 12 F.C. tablets

- 4 tablets of apremilast 10 mg
- 4 tablets of apremilast 20 mg
- 4 tablets of apremilast 30 mg



Maintenance Pack:

- A bottle contains 60 FC tablets of apremilast 30 mg

Dosing (Behçet disease, psoriasis, or psoriatic arthritis)

Dosing: Adult

- **Initial Dose: Children ≥6 years and adolescents, weighing ≥50 kg**

Day	Morning Dose	Evening Dose
Day 1	10 mg	Do Not Take a Dose
Day 2	10 mg	10 mg
Day 3	10 mg	20 mg
Day 4	20 mg	20 mg
Day 5	20 mg	30 mg
Day 6 onward	30 mg	30 mg

- **Maintenance dose:** 30 mg twice daily starting on day 6

Monitoring Parameters

- Monitor weight regularly during therapy
- Renal function
- Signs or symptoms of mood changes, depression, or suicidal thoughts
- Diarrhea or vomiting

Premilatic®
Apremilast

Add-on Therapy

Patient compliance

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PART
03

JAK Inhibitors Available in Iran

Rhofanib®
Tofacitinib

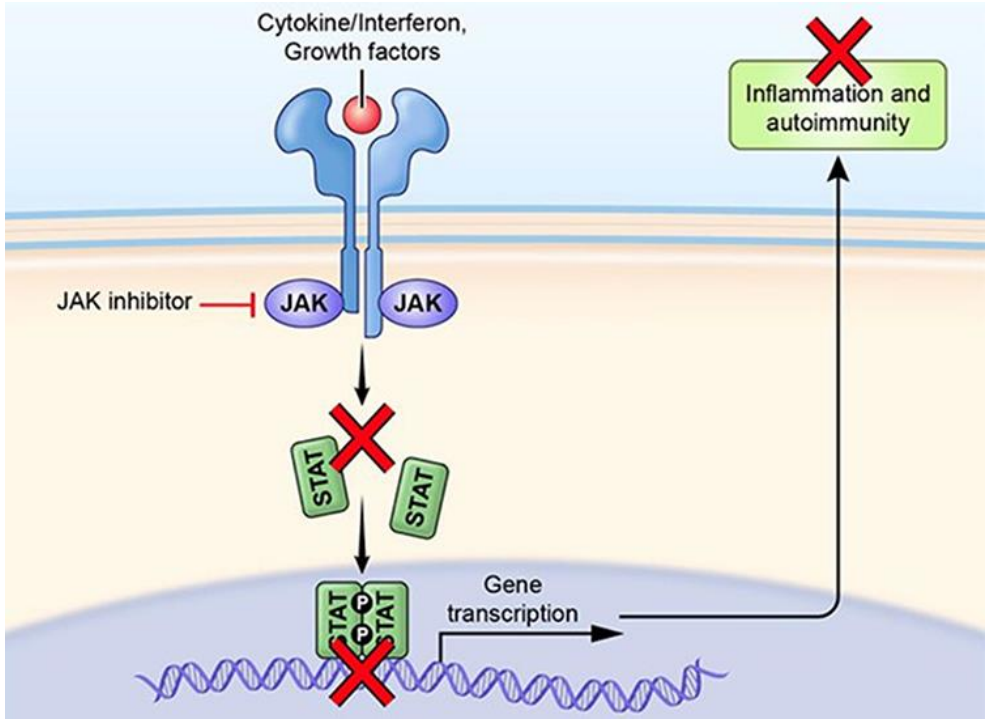
Intyma®
Baricitinib

Nupada®
Upadacitinib

JAK Inhibitors

Mechanism of action

These agents inhibit Janus kinase (JAK) enzymes, which are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. JAKs activate signal transducers and activators of transcription (STATs), which regulate gene expression and intracellular activity. The inhibition of JAKs prevents the activation of STATs.



JAK Inhibitors In Iran

For the first time in Iran, **NANOALVAND** has manufactured JAK inhibitor **tofacitinib (Rhofanib)** and made it available for thousands of patients who suffer from autoimmune diseases. A few years later, manufactured another JAK inhibitor **baricitinib (Intyma)** and now has the honor of introducing the newest molecule **upadacitinib (Nupada).**

Rhofanib®
Tofacitinib

→

Intyma®
Baricitinib

→

Nupada®
Upadacitinib

Generic Name:
Tofacitinib

Dosage Form:
IR Tablet 5 and 10 mg

Rhofanib®
Tofacitinib

Labeled Indications:

- Moderately to Severely Active Rheumatoid arthritis
- Active Ankylosing Spondylitis
- Active Psoriatic Arthritis
- Polyarticular Course Juvenile Idiopathic Arthritis
- Moderately to Severely Active Ulcerative colitis

Tofacitinib in Rheumatology

Rhofanib®
Tofacitinib

Adult Dosing

❑ **RA,AS,PSA:**

- 5 mg twice daily

Generic Name:
Baricitinib

Dosage Form:
IR Tablet 2 and 4 mg

Intyma® Baricitinib Labeled Indications:

- Severe Alopecia areata
- Moderately to severely active Rheumatoid arthritis
- COVID-19 in hospitalized patients

Intyma® Baricitinib

Adult Dosing

- Rheumatoid arthritis: 2 mg once daily

  - For use as adjunctive therapy in patients who have not met treatment goals despite maximally tolerated methotrexate therapy; may also be used off label as an alternative to methotrexate in disease-modifying antirheumatic drug (DMARD)–naive patients with moderate to high disease activity

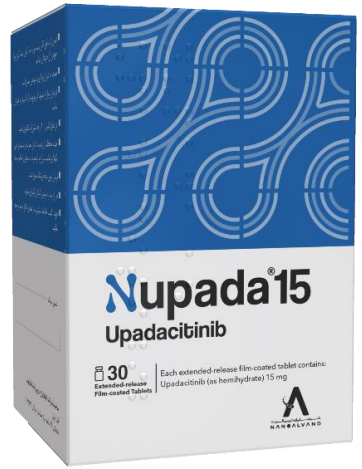
Generic Name:
Upadacitinib

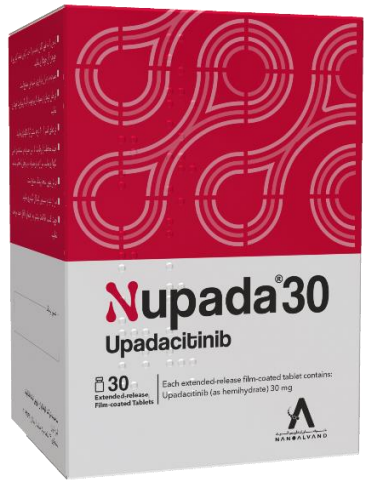
Dosage Form:
ER Tablets 15 and 30 mg

Nupada® Labeled Indications:

Upadacitinib

- Refractory Moderate to Severe Atopic Dermatitis
- Moderately to Severely Active Rheumatoid arthritis
- Active Ankylosing Spondylitis
- Active Non-radiographic Axial Spondyloarthritis
- Active Psoriatic Arthritis
- Polyarticular Juvenile Idiopathic Arthritis
- Moderately to Severely Active Ulcerative Colitis and Crohn's Disease





Upadacitinib in Rheumatology

Nupada®
Upadacitinib

Adult Dosing

❑ **RA,AS,PSA:**

- 15 mg once daily

Monitoring Parameters

- CBC diff and LFT: baseline and periodically thereafter
- Lipids: 4-8 weeks after therapy for Tofacitinib, 12 weeks after therapy for Baricitinib and Upadacitinib
- Viral hepatitis and TB (latent and active): prior to initiating therapy and periodically thereafter
- Abdominal symptoms
- Skin examinations: periodically, in patients at increased risk for skin cancer
- renal function and signs/symptoms of infections: baseline and periodicall thereafter
- Verify pregnancy status: prior to initiating therapy

Trexoma


Trexoma® 2.5
Methotrexate
100
Tablets
Each tablet contains:
Methotrexate 2.5 mg
NANOALVAND


Trexoma 30
Trexoma 25
Trexoma 20
Trexoma 15
Trexoma 10
Trexoma 7.5

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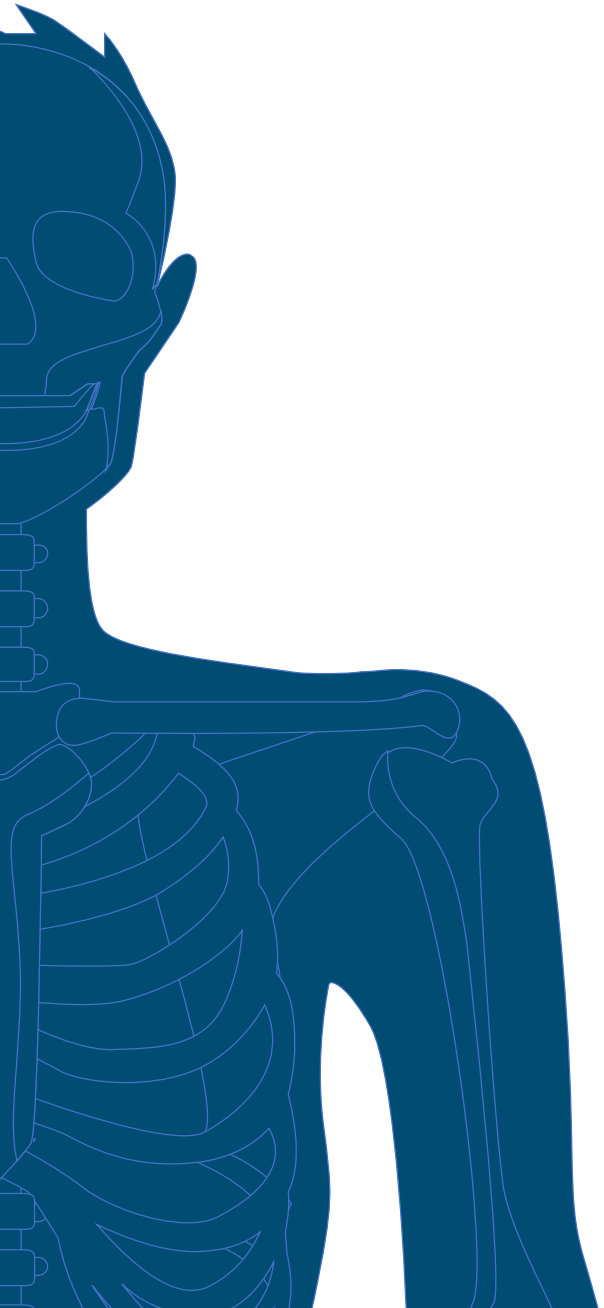
Osteoporosis



CinnoPar®

Teriparatide

600 mcg, 2.4 ml

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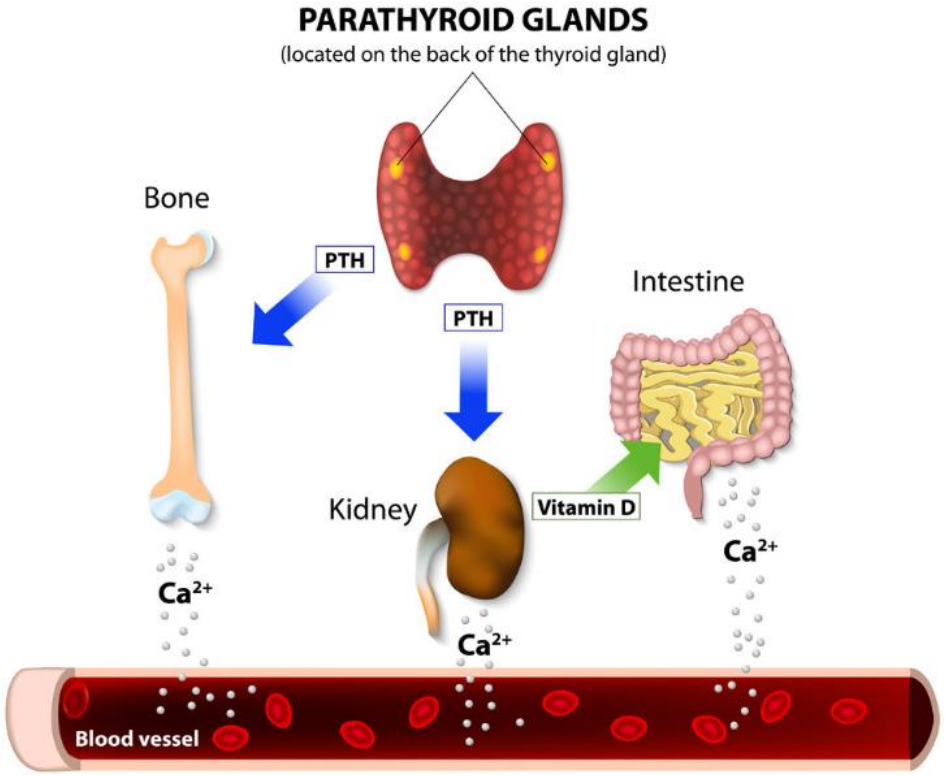
شرکت سیناژن

CinnaGen

Mechanism of Action

- ✓ **Teriparatide is a recombinant formulation of human PTH hormone that acts similarly to PTH hormone by stimulating osteoblast function, increasing calcium absorption from the digestive tract, and increasing calcium reabsorption from the kidneys**



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Teriparatide

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Unique mechanism of action

The first FDA approved
Anabolic agent for osteoporosis

PTH stimulates preosteoblasts to mature into bone-forming osteoblasts

Bone formation **begins** within the **first month** and **peaks 6 to 9 months** after initiation of daily PTH.

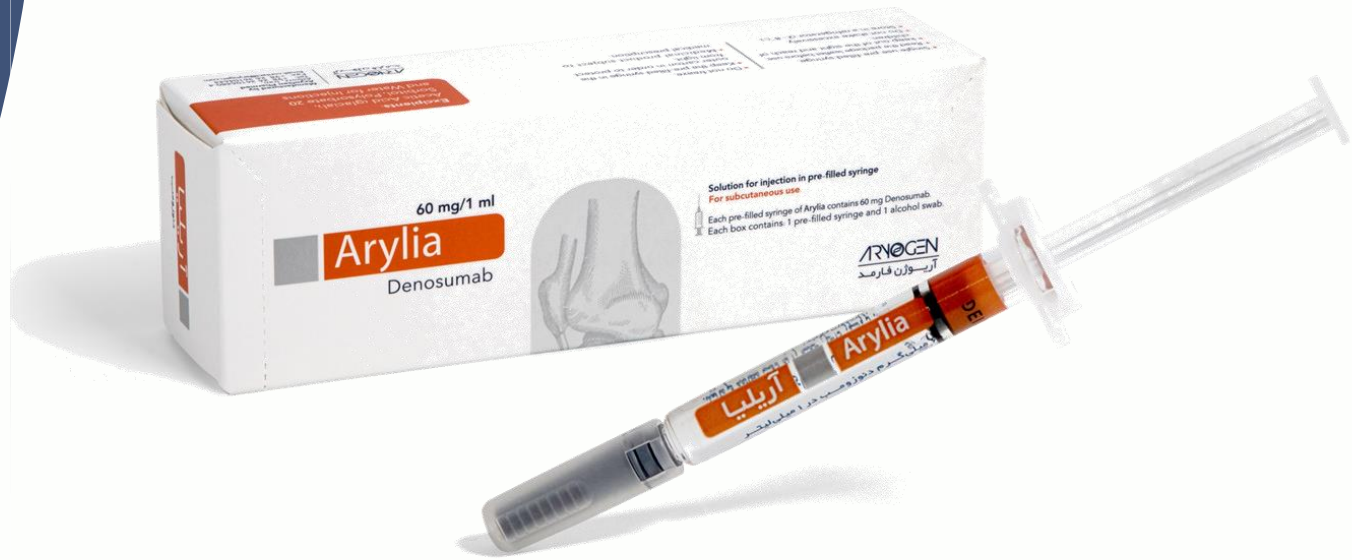
Labeled Indications

- Treatment of osteoporosis in postmenopausal women at high risk of frac
- Treatment of osteoporosis caused by long-term use of systemic glucocorticoids (greater than 5 mg of prednisone daily or equivalent) wh increases the risk of fracture
- Increasing bone mass in men at high risk of fracture due to sex hormone deficiency or osteoporosis
- Alternative therapy in patients who have not tolerated or responded adequately to other osteoporosis treatments

Monitoring Parameters

- Orthostatic hypotension
- BMD measurement at baseline and 1 to 2 years after starting treatment
- Serum calcium (at least 16 hours after drug injection)
- Urine calcium in patients suspected of having urinary stones or increased calcium
- If needed, monitor bone tests such as P1NP at baseline, 3 months, and 6 after starting treatment to assess response to treatment

Arylia



ARYOGEN
آریوژن فارمد

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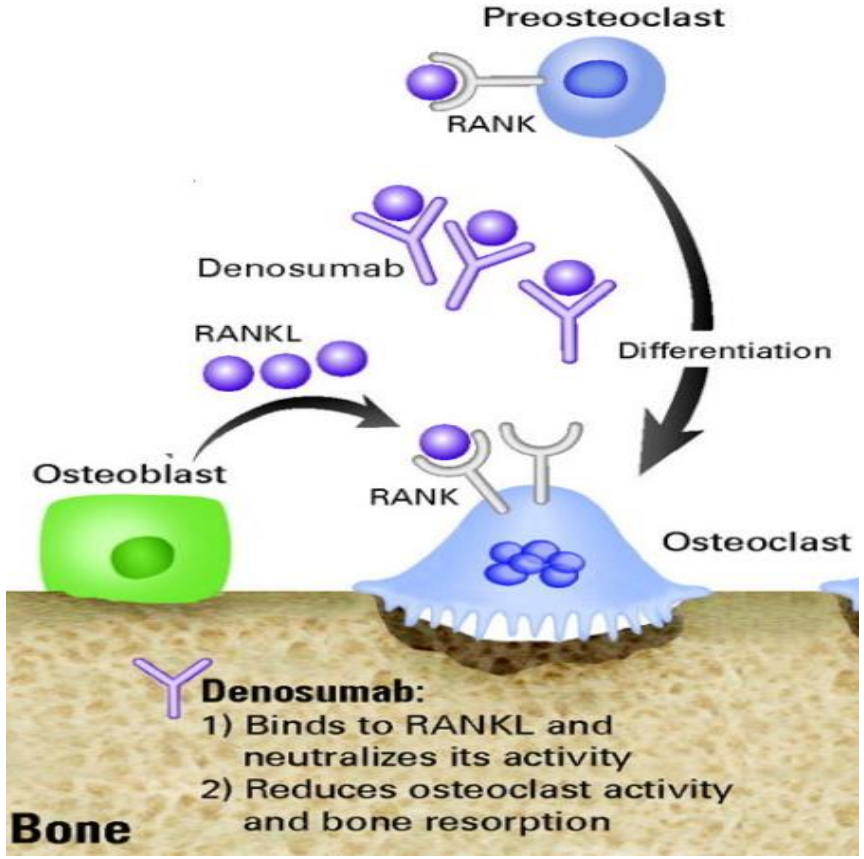
Mechanism of Action

➢ **Denosumab is a monoclonal antibody**

✓ Affinity for nuclear factor-kappa ligand (RANKL)

✓ Leading to **decreased bone resorption** and **increased bone mass in osteoporosis**.



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Indications

Arylia is indicated for the following conditions;
Osteoporosis and bone loss (to increase bone mass) Including:

- Androgen deprivation therapy-induced bone loss in males with prostate cancer
- Aromatase inhibitor-induced bone loss in females with breast cancer
- Glucocorticoid-induced osteoporosis
- Osteoporosis treatment in males and postmenopausal females at high risk of fracture

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Monitoring Parameters

- Serum creatinine, serum calcium, phosphorus and magnesium
- Pregnancy test
- Signs/symptoms of hypocalcemia, infection, or dermatologic reactions
- Routine oral exam
- Signs/symptoms of hypersensitivity
- Serial BMD at baseline and every 1 to 3 years

Renal Impairment

- **CrCl ≥30 mL/minute:**
  No dosage adjustment necessary
- **CrCl <30 mL/minute or on dialysis:**
  Monitor patients closely

Hepatic Impairment

- **No dosage adjustment necessary**

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Administration

Subcutaneously

↓

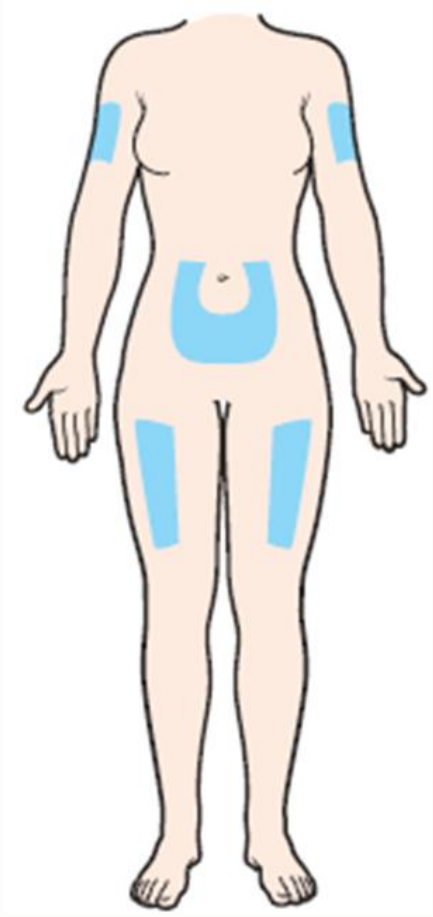
60 mg as a single dose

↓

Once every six months

↓

Preferred Sites:
upper arm, upper thigh, or abdomen



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01 In a refrigerator at 2°C to 8°C

02 Do not freeze

03 Protect Arylia from direct light and heat

04 Avoid vigorous shaking of Arylia

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Benefits

The only effective option in combination therapy with Teriparatide

Suitable for use in patients with renal impairment

Suitable for long-term use

Patient compliance

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Thank You for Your Attention

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Sky's the Limit

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