Apremilast (Otezla®)

Apremilast inhibits phosphodiesterase 4 (PDE4) specific for cyclin adenosine monophosphate (cAMP) which results in increases intracellular levels of inflammatory mediators (including TNF-alpha, and IL-23).

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Otezla Co-pay Card
Amgen Patient Assistance Foundation

FDA-Approved Indications and Dosing in Rheumatology

Apremilast is indicated for:

- Adult patients with active psoriatic arthritis (PsA)
- Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
- Adult patients with oral ulcers associated with Behçet's Disease
- Pediatric patients 6 years or older, weighing at least 20kg with severe plaque psoriasis

Oral Dosing

- Psoriatic Arthritis, plaque psoriasis and Behçet's Disease: To reduce risk of gastrointestinal symptoms, titrate to recommended dosage of 30 mg twice daily according to the following schedule

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 *& Thereafter*	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

- For adult patients with psoriatic arthritis, plaque psoriasis, Behcet's Disease with CrCl of <30 mg/min titrate using AM dose schedule only to target dose of 30mg once daily
- Pediatric plaque psoriasis:

Body Weight	Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 *& Thereafter*	
	AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
50 kg or more	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg
20 kg to less than 50 kg	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg

- For pediatric patients with CrCl of <30mL/min titrate according to AM schedule only to maximum of 20mg (20 to <50kg) or 30mg (>50kg)

Contraindications

Known hypersensitivity to apremilast or excipients

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Warnings and Precautions

1. Hypersensitivity: Cases of angioedema and anaphylaxis have been reported during post marketing surveillance. Avoid use in patients with known hypersensitivity to apremilast or to any of the excipients in the formulation. If signs or symptoms of serious hypersensitivity reactions develop during treatment, discontinue and institute appropriate therapy
2. Diarrhea, Nausea, and Vomiting: Consider dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
3. Depression: advise patients, their caregivers, and families to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes and if such changes occur to contact their healthcare provider. Carefully weigh risks and benefits of treatment
4. Weight loss: Monitor weight regularly.
5. Drug Interactions: Use with strong cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended because loss of efficacy may occur

Adverse Reactions (>5%)

- Diarrhea
- Nausea
- Upper respiratory tract infections
- Headache

Medication Strength and Preparations

- Available as 10mg, 20mg and 30mg tablets

Medication Administration and Storage

- Tablets should be stored at room temperature between 59°F to 86°F

Additional Considerations–Side effect management

- Diarrhea

1. Can consider dose reduction or interrupting therapy for severe diarrhea, nausea or vomiting. Most cases resolve within first few weeks of treatment.
2. Use caution in patients over 65 years of age and those who may be more susceptible to complications from diarrhea/vomiting.

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