Apremilast Therapeutic Cheat Sheet

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TRADE NAME

- OTEZLA®

MECHANISM OF ACTION[1]

- Apremilast inhibits phosphodiesterase 4 (PDE4) which prevents the degradation of cyclic adenosine monophosphate (cAMP). The resulting increase in cAMP results in an antagonistic effect on the production of proinflammatory cytokines

FDA APPROVED FOR[2,3]

- Adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
- Adult patients with active psoriatic arthritis
- Adult patients with oral ulcers associated with Behçet's Disease

OFF-LABEL USES[4-6]

- Lichen planus
- Behçet's disease
- Hidradenitis Suppurativa
- Nail and Scalp psoriasis
- Palmoplantar psoriasis
- Alopecia areata
- Atopic dermatitis

DOSING[1]

- Dosage titration schedule for Plaque Psoriasis, Psoriatic Arthritis, Oral Ulcers associated with Beçhet's Disease
  - Day 1: 10 mg
  - Day 2: 20 mg
  - Day 3: 30 mg
  - Day 4: 40 mg
  - Day 5: 50 mg
  - Day 6: 60 mg
  - Maintenance Dose: 30 mg PO twice daily
- Off-label dosage titration
  - Day 1: 10mg x 2 days
  - Day 3: 20mg x 2 days
  - Day 5: 30mg x 2 days
  - Day 7: 40mg x 2 days
  - Day 9: 50mg x 2 days
  - Day 11:60mg x 2 days
  - Maintenance Dose: 30 mg PO twice daily

SIDE EFFECTS[1]

- Most common side effects of Otezla® include:
  - Diarrhea
  - Nausea
  - Headache
  - Upper respiratory tract infection
  - Vomiting
  - Nasopharyngitis
  - Upper abdominal pain
  - Fatigue

WARNINGS[1]

- Hypersensitivity: Cases of angioedema and anaphylaxis have been reported during post marketing surveillance. Avoid the use of Otezla® 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 Otezla® and institute appropriate therapy
- Diarrhea, Nausea, and Vomiting: Consider Otezla® dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
- Weight Loss: Monitor weight regularly. If unexplained or clinically significant weight loss occurs, evaluate weight loss and consider discontinuation of Otezla®
- Drug Interactions: The use with strong cytochrome P450 enzyme inducers (such as rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended due to potential loss of efficacy
- Depression: Advise patients, their caregivers, and families to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes. If such mood changes occur, institute appropriate therapy.
  - It is recommended to carefully weigh risks and benefits of treatment with Otezla® in patients with a history of depression and/or suicidal thoughts or behavior

CONTRAINDICATIONS[1]

- Patients with known hypersensitivity to apremilast or any of the excipients in the formulation

PREGNANCY & BREASTFEEDING[1]

- Based on animal studies, apremilast may increase the risk for fetal loss
- Advise female patients of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential
- Apremilast has been detected in the milk of lactating mice. The risks and benefits should be considered before starting apremilast in a woman who is breastfeeding.

MONITORING[1]

- No recommended blood monitoring guidelines