

Apremilast Tablets



Product name

Generic name: Apremilast Tablets

English name: Apremilast Tablets

Chinese pronunciation: Apumisite Pian

Ingredient

Active ingredient: Apremilast

Excipients: Lactose, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate, Film coating (Opadry)

Description

Film-coated tablets, appears to be white or off-white after removing coating.

Indication

It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Strength

10mg/20mg/30mg

Dosage and administration

Dosage for Plaque Psoriasis Treatment

The recommended initial dosage titration of Apremilast Tablets from Day 1 to Day 5 is shown in Table 1. Following the 5-day titration, the recommended maintenance dosage is 30 mg twice daily taken orally starting on Day 6. This titration is intended to reduce the gastrointestinal symptoms associated with initial therapy.

Apremilast Tablets can be administered without regard to meals. Do not crush, split, or chew the tablets.

Table 1: Dosage Titration Schedule

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & there after	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10mg	10mg	10mg	10mg	20mg	20mg	20mg	20mg	30mg	30mg	30mg

Dosage Adjustment in Patients with Severe Renal Impairment

Apremilast Tablets dosage should be reduced to 30 mg once daily in patients with severe renal impairment (creatinine clearance (CLCr) of less than 30 mL per minute estimated by the Cockcroft-Gault equation). For initial dosage titration in this group, it is recommended that Apremilast Tablets be titrated using only the AM schedule listed in Table 1 and the PM doses be skipped.