

康契樂®
阿普米司特片



【Drug Name】

General Name: Apremilast Tablets

English Name: Apremilast Tablets

Chinese Pronunciation: Apumisite Pian

【Component】

Active Substance: Apremilast

Excipient: Lactose monohydrate, Cellulose microcrystalline, Croscarmellose sodium, Magnesium stearate, Film coating premix (gastric soluble type)

【Appearance】

It is a film-coated tablet, which appears to be white or almost white after removing the coating.

【Indication】

It is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who meet the criteria for receiving phototherapy or systemic therapy.

【Strength】

10mg/20mg/30mg

【Posology and method of administration】

Posology for the treatment of psoriasis

An initial dose titration schedule recommended for apremilast administered from Day 1 to Day 5 is shown below in Table 1. After these five days of dose titration, the recommended maintenance dose of apremilast is 30 mg taken orally twice daily starting from Day 6. The purpose of dose titration is to reduce gastrointestinal symptoms related with initial treatment.

It can be administered regardless of meals. Do not crush, break or chew the tablets.

Table 1. Dose titration 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

Dose adjustment for patients with severe renal insufficiency

The dose of apremilast should be reduced to 30 mg once daily in patients with severe renal insufficiency (creatinine clearance [Cl_{cr}] of less than 30 mL/min calculated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that apremilast be titrated using only the AM schedule listed in Table 1 and the PM doses be skipped.