Aprima™

Apremilast tablet

Presentation

Aprima™ 10 Tablet: Each tablet contains Apremilast INN 10 mg.
Aprima™ 30 Tablet: Each tablet contains Apremilast INN 30 mg.

Description

Apremilast is an inhibitor of phosphodiesterase 4 (PDE4) enzyme specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. The specific mechanism by which Apremilast exerts its therapeutic action in psoriatic arthritis patients and psoriasis patients is not well defined.

Indication

Apremilast is indicated for the treatment of adult patients with active psoriatic arthritis and moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

Dosage and Administration

The recommended initial dosage titration of Apremilast from Day 1 to Day 5 is shown below. 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 can be administered without regard to meals.

Day 1: 10 mg in morning
Day 2: 10 mg in morning and 10 mg in evening
Day 3: 10 mg in morning and 20 mg in evening
Day 4: 20 mg in morning and 20 mg in evening
Day 5: 20 mg in morning and 30 mg in evening
Day 6 and thereafter: 30 mg twice daily

Dosage adjustment in patients with severe renal impairment

Apremilast dosage should be reduced to 30 mg once daily in patients with severe renal impairment. For initial dosage titration, it is recommended that Apremilast be titrated using only the morning schedule and the evening doses be skipped.

Contraindications

Apremilast is contraindicated in patients with a known hypersensitivity to Apremilast or to any of the excipients in the formulation.

Precautions

Treatment with Apremilast is associated with an increase in adverse reactions of depression. Patients, their caregivers and families should be advised of the need 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. Prescribers should carefully evaluate the risks and benefits of continuing treatment with Apremilast if such events occur.

During the controlled period of the studies in psoriatic arthritis, weight decrease between 5%-10% of body weight was reported in 10% of subjects treated with Apremilast 30 mg twice daily compared to 3.3% treated with placebo.

Drug interactions

Co-administration of strong cytochrome P450 enzyme inducer rifampin resulted in a reduction of systemic exposure of Apremilast. Therefore, the use of cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with Apremilast is not recommended.

Side-effects

The most frequently occurring side effects of Apremilast are nausea, diarrhea, and headache.
Other less frequent side effects are upper respiratory tract infection, vomiting, nasopharyngitis, abdominal pain, hypersensitivity, gastroesophageal reflux disease, dyspepsia, fatigue, decrease appetite, cough, rash, insomnia.

Use in pregnancy and lactation

Pregnancy: Pregnancy Category C.

Nursing mothers: It is not known whether Apremilast or its metabolites are present in human milk; however Apremilast was detected in milk of lactating mice. Caution should be exercised when Apremilast is administered to a nursing woman.

Use in pediatric patients

The safety and effectiveness of Apremilast in pediatric patients less than 18 years of age have not been established.

Commercial Packaging

Aprima™ 10 Tablet: Each box contains 2 Alu-PVC blister strips of 10 tablets.
Aprima™ 30 Tablet: Each box contains 2 Alu-PVC blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh

V.N.02

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