

**Composition : Aprila-10 Tablet:** Each Film Coated Tablet Contains Apremilast INN 10 mg.

**Aprila Tablet:** Each Film Coated Tablet Contains Apremilast INN 30 mg.

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

**Dosage and administration :** To reduce risk of gastrointestinal symptoms, titrate to recommended dose of 30 mg twice daily starting on day 6 according to the following 5 day titration schedule :

| 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 in Severe Renal Impairment:**

| Recommended dose is 30 mg once daily.

Or, as directed by the registered physicians.

**Side effects :** The most common side effects are nausea, diarrhea, headache and upper respiratory tract infection.

**Contraindication :** Apremilast is contraindicated in patients with known hypersensitivity to Apremilast or any other components of this product.

**Drug interactions :** Concomitant use of this medicine with strong Cytochrome P450 enzyme inducers (e.g., Rifampin,

**Aprila**  
Tablet



Phenobarbital, Carbamazepine, Phenytoin) is not recommended because loss of efficacy may occur.

**Precautions :** Caution should be exercised when using in patients with a history of depression and suicidal thoughts or other behavior. Monitor body weight regularly.

**Use in pregnancy and lactation :** Pregnancy category C. There are no adequate and well controlled studies in pregnant woman. This product should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this medicine is excreted in human milk. Caution should be exercised when this product is administered to a nursing woman.

**Overdose :** In case of overdose, patients should seek immediate medical help. Patients should be managed by symptomatic and supportive care should there be an overdose.

**Storage :** Store below 25°C in a dry place.

**Packing : Aprila-10 Tablet:** Each box contains 1x14's tablets in blister pack.

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