

APREZO FILM COATED TABLET

Apremilast 10mg, 20mg, 30mg

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What APREZO is used for

Apremilast is indicated for:

- Apremilast, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.
- The treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

How APREZO works

Psoriatic arthritis and psoriasis are usually lifelong conditions and there is currently no cure. Apremilast works by reducing the activity of an enzyme in the body called 'phosphodiesterase 4', which is involved in the process of inflammation. By reducing the activity of this enzyme, Apremilast can help to control the inflammation associated with psoriatic arthritis and psoriasis, and thereby reduce the signs and symptoms of these conditions.

In psoriatic arthritis, treatment with Apremilast results in an improvement in swollen and painful joints, and can improve your general physical function.

In psoriasis, treatment with Apremilast results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

Apremilast has also been shown to improve the quality of life in patients with psoriasis or psoriatic arthritis. This means that the impact of your condition on daily activities, relationships and other factors should be less than it was before.

Before you use APREZO

- When you must not use it

If you are allergic to apremilast or any of the other ingredients of this medicine.

During pregnancy and in nursing women

- Before you start to use it

Talk to your doctor or pharmacist before taking Apremilast Tablet. Symptoms you should be aware of: If your doctor considers you to be underweight, and you observe an unintentional loss of body weight while being treated with apremilast, you should talk to your doctor.

If you have severe kidney problems then the recommended dose of apremilast is 30 mg once a day (morning dose). Your doctor will talk to you about how to increase your dose when you first start taking apremilast.

Before starting treatment with apremilast, inform your doctor if you are suffering from symptoms of worsening depression with suicidal thinking or behaviour especially if you take any additional medicines since some of those could increase the probability of these side effects. You or your caregiver should also immediately inform your doctor of any changes in behaviour or mood and of any suicidal thoughts you may have. You may also experience sleeplessness, or depressive mood.

If you experience severe diarrhea, nausea, or vomiting, you should talk to your doctor.

Pediatric patients

The safety and effectiveness of apremilast in pediatric patients less than 18 years of age have not been established. Therefore it is not

recommended for use in pediatric patients aged less than 18 years.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because apremilast can affect the way some other medicines work. Also some other medicines can affect the way apremilast works. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because apremilast can affect the way some other medicines work. Also some other medicines can affect the way apremilast works.

In particular, tell your doctor or pharmacist before taking apremilast if you are taking any of the following medicines:

- rifampicin – an antibiotic used for tuberculosis
- phenytoin, phenobarbital and carbamazepine - medicines used in the treatment of seizures or epilepsy

How to use APREZO

- How much to use

The recommended initial dosage titration of apremilast from Day 1 to Day 5 is shown in table below. Your treatment will start at a lower dose and will gradually be increased over the first 6 days of treatment. The recommended dose of apremilast is 30 mg twice a day after the titration phase is complete – one 30 mg dose in the morning and one 30 mg dose in the evening, approximately 12 hours apart, with or without food.

Dosage Titration Schedule

Day 1	Day 2	
AM	AM	PM
10 mg	10 mg	10 mg

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Day 3		Day 4	
AM	PM	AM	PM
10 mg	20 mg	20 mg	20 mg

Day 5		Day 6 & thereafter	
AM	PM	AM	PM
20 mg	30 mg	30 mg	30 mg

People with kidney problems
If you have severe kidney problems then the recommended dose of apremilast is 30 mg once a day (morning dose). Your doctor will talk to you about how to increase your dose when you first start taking apremilast.

- When to use it

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

- You should continue taking apremilast until your doctor tells you to stop.
- Do not stop taking apremilast without talking to your doctor first. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

- If you miss a dose of apremilast, take it as soon as you remember. If it is close to the time for your next dose, just skip the missed dose. Take the next dose at your regular time.
- Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take more apremilast than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack and this leaflet with you.

While you are using it

- Things you must do

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Swallow the tablets whole, preferably with water.
- You can take the tablets either with or without food.
- Take apremilast at about the same time each day, one tablet in the morning and one tablet in the evening.

- Things you must not do

Do not stop using the medicine unless advised by your doctor. Do not use any new medicines without consulting your doctor or pharmacist. Do not give APREZO to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- If your condition has not improved after six months of treatment, you should talk to your doctor.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Psoriatic Arthritis:

Most common adverse reactions:

- diarrhea (1.8%),
- nausea (1.8%)
- headache (1.2%)
- Upper respiratory tract infection
- Vomiting
- Nasopharyngitis
- Abdominal pain upper

Other adverse reactions:

- Immune system disorders: Hypersensitivity
- Investigations: Weight decrease
- Gastrointestinal Disorders: Frequent bowel movement, gastroesophageal reflux disease, dyspepsia
- Metabolism and Nutrition Disorders: Decreased appetite*
- Nervous System Disorders: Migraine
- Respiratory, Thoracic, and Mediastinal Disorders: Cough
- Skin and Subcutaneous Tissue Disorders: Rash

Psoriasis:

Most common adverse reactions:

- diarrhea (1.0%),
- nausea (1.6%),
- upper respiratory tract infection, and
- headache (0.8%), including tension headache.

Other adverse reactions:

- Abdominal pain
- Vomiting
- Fatigue
- Dyspepsia
- Decreased appetite
- Insomnia
- Back pain
- Migraine
- Frequent bowel movements
- Depression
- Bronchitis
- Tooth abscess
- Folliculitis
- Sinus headache

Severe worsening of psoriasis (rebound) occurred in 0.3% subjects following discontinuation of treatment with apremilast.

If you are 65 years of age or older, you might have higher risk of complications of severe diarrhea, nausea and vomiting.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and Disposal of APREZO

- Storage

Keep this medicine out of the sight and reach of children.

- Disposal

Do not use this medicine after the expiry date which is stated on the carton.

Blisters: Store below 30°C.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment

Product Registration Holder

Glenmark Pharmaceuticals
(Malaysia) Sdn Bhd (660397-W)
D-31-02, Menara Suezcap 1,
No. 2, Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

Date of Revision

- 27/12/2021

Serial Number

NPRA (R2)21/180

Product Description

- What it looks like

Apremilast 10 mg : White coloured, round shaped, biconvex film coated tablet, with beveled edges, debossed with '96' on one side and 'G' on another side.

Apremilast 20 mg : White coloured, round shaped, biconvex film coated tablet, with beveled edges, debossed with '56' on one side and 'G' on another side.

Apremilast 30 mg : White coloured, round shaped, biconvex film coated tablet, with beveled edges, debossed with '510' on one side and 'G' on another side.

- Ingredients

- Active ingredient
Apremilast

- Inactive ingredients
Lactose Monohydrate ,
Croscopovidone , Magnesium Stearate ,
Corn Starch dried Opadry White,
Purified water , Hypromellose ,
Titanium Dioxide , Macrogol

- MAL number:

Manufacturer

Glenmark Pharmaceuticals Ltd
Plot No. 2, Phase –II,
Pharma Zone, SEZ,
Pithampur, Dist. Dhar
Madhya Pradesh – 454775.
INDIA.