Clean Patient Information Leaflet

SCHEDULING STATUS: [S4]

APREMILAST 10 mg GLENMARK: (Tablet)

APREMILAST 20 mg GLENMARK: (Tablet)

APREMILAST 30 mg GLENMARK: (Tablet)

Apremilast

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you take APREMILAST GLENMARK:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **APREMILAST GLENMARK** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What APREMILAST GLENMARK is and what it is used for

APREMILAST GLENMARK is an immunosuppressant medicine (medicine that prevent activity of the immune system) that is used in the treatment of:

Clean Patient Information Leaflet

- *Psoriatic arthritis* (a form of inflammatory arthritis that affects some people who have the skin condition psoriasis).
- *Psoriasis* (a condition in which skin cells build up and form scales and itchy patches).

2. What you need to know before you take APREMILAST GLENMARK

Do not take APREMILAST GLENMARK:

- If you are hypersensitive (allergic) or have had a previous allergic reaction to any of the other ingredients of **APREMILAST GLENMARK** (listed in *section 6*)
- If you are pregnant

Warnings and precautions

Take special care by telling your doctor or health care provider:

- If you develop diarrhoea, nausea and vomiting
- If you have or have had any psychiatric disorder such as depression and/or suicidal thoughts
- If you are underweight
- If you have or have had any kidney problems

Other medicines and APREMILAST GLENMARK

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor if you are taking any medicine such as:

- Rifampicin (an antibiotic used to treat tuberculosis (TB))
- Phenobarbital (an anticonvulsant medicine used to treat certain types of epilepsy)
- Carbamazepine (an anticonvulsant medicine used for the treatment of seizures)
- Phenytoin (an anti-epileptic medicine used to treat seizures)
- St. John's Wort (a herbal medicine used for the treatment of depression)

Clean Patient Information Leaflet

- Corticosteroids (medicines used to control inflammation)
- Coal tar shampoo
- Salicylic acid scalp preparations
- Ketoconazole (an antifungal medicine used to treat fungal infections)
- Methotrexate (a chemotherapy medicine that suppresses the immune system)
- Oral contraceptives (the pill).

APREMILAST GLENMARK with food and drink

APREMILAST GLENMARK can be taken with or without food.

Do not crush, split, or chew the tablets.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **APREMILAST GLENMARK**.

Pregnancy:

You should not use **APREMILAST GLENMARK** if you are pregnant (see **Do not take APREMILAST GLENMARK** above). You should also not become pregnant during treatment with **APREMILAST GLENMARK** and you should use an effective method of contraception. If you get pregnant during your treatment, you must immediately inform your doctor.

Breastfeeding:

It is not known if **APREMILAST GLENMARK** is present in human breast milk. You must not breastfeed while you are treated with **APREMILAST GLENMARK**.

Driving and using machines

APREMILAST GLENMARK may cause fatigue. It is not always possible to predict to what extent

Clean Patient Information Leaflet

APREMILAST GLENMARK may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which **APREMILAST GLENMARK** affects your ability to perform them.

APREMILAST GLENMARK contains lactose

APREMILAST GLENMARK contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take APREMILAST GLENMARK

Do not share medicines prescribed for you with any other person.

Always take **APREMILAST GLENMARK** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

APREMILAST GLENMARK is taken at a low dose on day 1. The dose is then increased as shown in the table below. The usual long-term dose is 30 mg twice a day.

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 and 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

Your doctor will tell you how long your treatment with **APREMILAST GLENMARK** will last. Do not stop early, because this can cause your symptoms to return.

If you have the impression that the effect of **APREMILAST GLENMARK** is too strong or too weak, tell your doctor or pharmacist.

The safety and efficacy of apremilast, as contained in **APREMILAST GLENMARK**, in children < 18 years have not been established.

Clean Patient Information Leaflet

If you take more APREMILAST GLENMARK than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you forget to take APREMILAST GLENMARK

If you forgot to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

APREMILAST GLENMARK can have side effects.

Not all side effects reported for **APREMILAST GLENMARK** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **APREMILAST GLENMARK**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **APREMILAST GLENMARK** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Severe headache.

These are all very serious side effects. If you have them, you may have had a serious reaction to **APREMILAST GLENMARK**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- Diarrhoea (loose or watery bowel movements three or more times a day)

Clean Patient Information Leaflet

- Nausea (stomach discomfort and the sensation of wanting to vomit)
- Vomiting (emptying of stomach)
- Upper stomach pain
- Back pain
- Nasopharangitis (the common cold)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent adverse reactions:

- Bronchitis
- Upper respiratory tract infection
- Decreased appetite
- Insomnia
- Depression
- Cough
- Dyspepsia
- Frequent bowel movements
- Gastroesophageal reflux disease
- Fatigue (an overall feeling of tiredness and lack of energy)

Less frequent adverse reactions

- Suicidal ideation and behaviour
- Gastrointestinal haemorrhage
- Rash
- Urticaria
- Weight decrease

Clean Patient Information Leaflet

Adverse reactions with unknown frequency

- Angioedema

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **APREMILAST GLENMARK**.

5. How to store APREMILAST GLENMARK

Store all medicines out of reach of children.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What APREMILAST GLENMARK contains

- The active ingredient is apremilast.
- The other ingredients are corn starch (dried), crospovidone type A, lactose monohydrate, magnesium stearate, Opadry 03F580037 White, purified water.

What APREMILAST GLENMARK looks like and contents of the pack

Two-week starter pack:

Tablet strength: 13-tablets blister titration pack containing: (4) 10-mg, (4) 20- mg, and (5) 30-mg tablets with an additional (14) 30-mg

Packaging material: Alu-Alu blister pack and PVC/PVdC/PVC blister pack.

Clean Patient Information Leaflet

28-Count carton:

Tablet strength: Two 30-mg blisters containing (14) 30- mg tablets

Packaging material: Alu-Alu blister pack and PVC/PVdC/PVC blister pack.

56-Count carton:

Tablet strength: 13-tablets blister titration pack containing: (4) 10-mg, (4) 20- mg, and (5) 30-mg tablets with an additional (42) 30-mg tablets.

Packaging material: Alu-Alu blister pack and PVC/PVdC/PVC blister pack.

Holder of Certificate of Registration

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