Package leaflet: Information for the patient

Apremilast Clonmel 10 mg film-coated tablets
Apremilast Clonmel 20 mg film-coated tablets
Apremilast Clonmel 30 mg film-coated tablets
apremilast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Apremilast Clonmel is and what it is used for
2. What you need to know before you take Apremilast Clonmel
3. How to take Apremilast Clonmel
4. Possible side effects
5. How to store Apremilast Clonmel
6. Contents of the pack and other information

1. What Apremilast Clonmel is and what it is used for

What Apremilast Clonmel is

Apremilast Clonmel contains the active substance 'apremilast'. This belongs to a group of medicines called phosphodiesterase 4 inhibitors, which help to reduce inflammation.

What Apremilast Clonmel is used for

Apremilast Clonmel is used to treat adults with the following conditions:
- **Active psoriatic arthritis** - if you cannot use another type of medicine called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) or when you have tried one of these medicines and it did not work.
- **Moderate to severe chronic plaque psoriasis** - if you cannot use one of the following treatments or when you have tried one of these treatments and it did not work:
  - phototherapy - a treatment where certain areas of skin are exposed to ultraviolet light
  - systemic therapy - a treatment that affects the entire body rather than just one local area, such as 'ciclosporin', 'methotrexate' or 'psoralen'.
- **Behçet's disease (BD)** - to treat the mouth ulcers which is a common problem for people with this illness.

Apremilast is used to treat children and adolescents 6 years of age and older and weighing at least 20 kg with the following condition:
- **Moderate to severe plaque psoriasis** – if your doctor determines that it is appropriate for you to take a systemic therapy like Apremilast Clonmel.

What psoriatic arthritis is

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis, an inflammatory disease of the skin.

What plaque psoriasis is

Psoriasis is an inflammatory disease of the skin, which can cause red, scaly, thick, itchy, painful patches on your skin and can also affect your scalp and nails.

What Behçet's disease is

Behçet's disease is a rare type of inflammatory disease which affects many parts of the body. The most common problem is mouth ulcers.

How Apremilast Clonmel works

Psoriatic arthritis, psoriasis and Behçet's disease are usually lifelong conditions and there is currently no cure. Apremilast Clonmel 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 Clonmel can help to control the inflammation associated with psoriatic arthritis, psoriasis and Behçet's disease, and thereby reduce the signs and symptoms of these conditions.

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

In adults and in children and adolescents from the age of 6 years and weighing at least 20 kg with psoriasis, treatment with apremilast results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

In adults with Behçet's disease, treatment with Apremilast Clonmel reduces the number of mouth ulcers and can stop them completely. It can also reduce the associated pain.

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

2. What you need to know before you take Apremilast Clonmel

DO NOT take Apremilast Clonmel:

- if you are allergic to apremilast or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or think you may be pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking Apremilast Clonmel.

Depression and suicidal thoughts

Tell your doctor before starting Apremilast Clonmel if you have depression which is getting worse with thoughts of suicide.

You or your caregiver should also tell your doctor straight away of any changes in behaviour or mood, feelings of depression and of any suicidal thoughts you may have after taking Apremilast Clonmel.

Severe kidney problems

If you have severe kidney problems, your dose will be different – see section 3.

If you are underweight

Talk to your doctor while taking Apremilast Clonmel if you lose weight without meaning to.

Gut problems

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

Children and adolescents

Apremilast Clonmel is not recommended for use in children who have moderate to severe plaque psoriasis and are below 6 years of age or weigh less than 20 kg, because it has not been studied in these age and weight groups.
Apremilast Clonmel is not recommend for use in children and adolescents below 18 years of age in other indications, because safety and efficacy have not been established in this age group.

Other medicines and Apremilast Clonmel

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 Clonmel can affect the way some other medicines work. Also some other medicines can affect the way Apremilast Clonmel works.

In particular, tell your doctor or pharmacist before taking Apremilast Clonmel 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
- St John's Wort – a herbal medicine for mild anxiety and depression.

Pregnancy and breast-feeding

Do not take Apremilast Clonmel if you are pregnant or think you may be pregnant.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
There is little information about the effects of Apremilast Clonmel in pregnancy. You should not become pregnant while taking this medicine and should use an effective method of contraception during treatment with Apremilast Clonmel.
It is not known if this medicine passes into human milk. You should not use Apremilast Clonmel while breast-feeding.

Driving and using machines

Apremilast Clonmel has no effect on the ability to drive and use machines.

Apremilast Clonmel contains lactose and sodium

Apremilast Clonmel contains lactose (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.

This medicine contains less than 1 mmol sodium (23 mg) per recommended dose (30 mg twice daily), that is to say essentially 'sodium-free'.

3. How to take Apremilast Clonmel

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

How much to take

- When you first start taking Apremilast Clonmel, you will receive a 'treatment initiation pack' which contains enough tablets for a total of two weeks of treatment.
- The 'treatment initiation pack' is clearly labelled to make sure you take the correct tablet at the correct time.
- Your treatment will start at a lower dose and will gradually be increased during the first week of treatment (titration phase).
- The 'treatment initiation pack' will also contain enough tablets for another week at the recommended dose.
- Apremilast ClonmelOnce the recommended dose has been reached, you will only get a single tablet strength in your prescribed packs.
- You will only ever need to go through the stage of gradually increasing your dose once even if you re-start treatment.

Adults

- The recommended dose of Apremilast Clonmel for adult patients is 30 mg twice a day after the titration phase is completed, as shown in the table below - one 30 mg dose in the morning and one 30 mg dose in the evening, approximately 12 hours apart, with or without food. This is a total daily dose of 60 mg.

Day	**Morning dose**	**Evening dose**	**Total daily dose**
Day 1	10 mg (pink)	Do not take a dose	10 mg
Day 2	10 mg (pink)	10 mg (pink)	20 mg
Day 3	10 mg (pink)	20 mg (brown)	30 mg
Day 4	20 mg (brown)	20 mg (brown)	40 mg
Day 5	20 mg (brown)	30 mg (beige)	50 mg
Day 6 onwards	30 mg (beige)	30 mg (beige)	60 mg

Children and adolescents 6 years of age and older

- The Apremilast Clonmel dose will be based on body weight.

*For patients who weigh from 20 kg to less than 50 kg **: The recommended dose of apremilast is 20 mg twice a day, after the titration phase is completed, as shown in the table below - one 20 mg dose in the morning and one 20 mg dose in the evening, approximately 12 hours apart, with or without food. This is a total daily dose of 40 mg.

	Weight of 20 kg to less than 50 kg *		
Day	**Morning dose**	**Evening dose**	**Total daily dose**
Day 1	10 mg	Do not take a dose	10 mg
Day 2	10 mg	10 mg	20 mg
Day 3	10 mg	20 mg	30 mg
Day 4	20 mg	20 mg	40 mg
Day 5	20 mg	20 mg	40 mg
Day 6 onwards	20 mg	20 mg	40 mg

* There are no dosage packages for Apremilast Clonmel that allow for titration and maintenance of

treatment in paediatric patients weighing 20 kg to less than 50 kg. Thus, it is not possible to treat paediatric patients weighing 20 kg to less than 50 kg with Apremilast Clonmel; other apremilast products offering these dosage packages should be used insteadApremilast Clonmel.

For patients who weigh at least 50 kg: The recommended dose of Apremilast Clonmel is 30 mg twice a day after the titration phase is completed (the same as the adult dose), as shown in the table below - one 30 mg dose in the morning and one 30 mg dose in the evening, approximately 12 hours apart, with or without food. This is a total daily dose of 60 mg.

	Weight of 50 kg or more		
Day	**Morning dose**	**Evening dose**	**Total daily dose**
Day 1	10 mg (pink)	Do not take a dose	10 mg
Day 2	10 mg (pink)	10 mg (pink)	20 mg
Day 3	10 mg (pink)	20 mg (brown)	30 mg
Day 4	20 mg (brown)	20 mg (brown)	40 mg
Day 5	20 mg (brown)	30 mg (beige)	50 mg
Day 6 onwards	30 mg (beige)	30 mg (beige)	60 mg

Patients with severe kidney problems

If you are an adult with severe kidney problems, then the recommended dose of Apremilast Clonmel is 30 mg **once a day (morning dose)**.

In children and adolescents 6 years of age and older with severe renal impairment, the recommended dose of Apremilast Clonmel is 30 mg **once a day (morning dose)** for patients who weigh at least 50 kg, and for children who weigh 20 kg to less than 50 kg the recommended dose of apremilast is **20 mg once a day (morning dose)**.

Your doctor will talk to you about how to increase your dose when you first start taking Apremilast Clonmel. Your doctor may advise that you only take the morning dose shown in the table above that applies to you (for adults or for children/adolescents) and that you skip the evening dose.

How and when to take Apremilast Clonmel

- Apremilast Clonmel is for oral use.
- Swallow the tablets whole, preferably with water, in order to avoid damage to the film-coating.
- You can take the tablets either with or without food.
- Take Apremilast Clonmel at about the same time each day, one tablet in the morning and one tablet in the evening.

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

If you take more Apremilast Clonmel than you should

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

If you forget to take Apremilast Clonmel

- If you miss a dose of Apremilast Clonmel, 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 stop taking Apremilast Clonmel

- You should continue taking Apremilast Clonmel until your doctor tells you to stop.
- Do not stop taking Apremilast Clonmel without talking to your doctor first.

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

4. Possible side effects

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

Serious side effects – depression and suicidal thoughts

Tell your doctor straight away about any changes in behaviour or mood, feelings of depression, thoughts of suicide or suicidal behaviour (this is uncommon).

Very common side effects (may affect more than 1 in 10 people)
- diarrhoea
- nausea
- headache
- upper respiratory tract infections such as cold, runny nose, sinus infection

Common side effects (may affect up to 1 in 10 people)
- cough
- back pain
- vomiting
- feeling tired
- stomach pain
- loss of appetite
- frequent bowel movements
- difficulty sleeping (insomnia)
- indigestion or heartburn
- inflammation and swelling of the tubes in your lungs (bronchitis)
- common cold (nasopharyngitis)
- depression
- migraine
- tension headache

Uncommon side effects (may affect up to 1 in 100 people)
- rash
- hives (urticaria)
- weight loss
- allergic reaction
- bleeding in the bowel or in the stomach
- suicidal ideation or behaviour
- anxiety
- mood changes

Not known side effects (frequency cannot be estimated from the available data):
- severe allergic reaction (may include swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing)

If you are 65 years of age or older, you might have a higher risk of complications of severe diarrhoea, nausea and vomiting. If your gut problems become severe, you should talk to your doctor.

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. You can also report side effects directly via:
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Apremilast Clonmel

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

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Apremilast Clonmel contains

The active substance is apremilast.
Each tablet contains 10 mg, 20 mg or 30 mg apremilast.

The other ingredients are:
Tablet core: powdered cellulose, lactose monohydrate, calcium carbonate, pregelatinised maize starch, crospovidone, sodium stearyl fumarate

Film-coating 10 mg tablets: hypromellose (E 464), macrogol (E 1521), titanium dioxide (E 171), iron oxide red (E 172)

Film-coating 20 mg tablets: hypromellose (E 464), macrogol (E 1521), titanium dioxide (E 171), iron oxide yellow (E 172), iron oxide red (E 172)

Film-coating 30 mg tablets: hypromellose (E 464), titanium dioxide (E 171), macrogol (E 1521), iron oxide red (E 172), iron oxide yellow (E 172), iron oxide black (E 172)

What Apremilast Clonmel looks like and contents of the pack

Apremilast Clonmel 10 mg film-coated tablets
Pink, oval, biconvex (8 mm in length and 4 mm in width).

Apremilast Clonmel 20 mg film-coated tablets
Brown, oval, biconvex (10 mm in length and 5 mm in width).

Apremilast Clonmel 30 mg film-coated tablets
Beige, oval, biconvex (13 mm in length and 6 mm in width).

Pack sizes
Apremilast Clonmel 30 mg is available in PVC/Alu foil blisters containing 56 or 168 film-coated tablets or PVC/Alu foil unit-dose blisters containing 56 x 1 or 168 x 1 film-coated tablets.

Apremilast Clonmel 10 mg, 20 mg and 30 mg is available in PVC/Alu foil blisters containing 27 film-

coated tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg) or PVC/Alu unit-dose foil blisters containing 27 x 1 film-coated tablets (4 x 10 mg, 4 x 20 mg, 19 x 30 mg).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
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Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland
~~STADA Arzneimittel GmbH, Austria, Muthgasse 36/2, 1190 Vienna, Austria~~
~~Centrafarm Services B.V., Van de Reijtstraat 31-E, 4814 NE Breda, The Netherlands~~

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria:	Apremilast STADA 30 mg Filmtabletten
	Apremilast STADA Starterpackung 10 mg + 20 mg + 30 mg Filmtabletten
Belgium:	Apremilast EG 30 mg filmomhulde tabletten
	Apremilast EG 10 mg + 20 mg + 30 mg filmomhulde tabletten
Cyprus:	APREMILAST/STADA 30 mg επικαλυμμένα με λεπτό υμένιο δισκία
	APREMILAST/STADA 10 mg/20 mg/30 mg επικαλυμμένα με λεπτό υμένιο δισκία
Denmark:	Apremilast STADA
Germany:	Apremilast STADA 30 mg Filmtabletten
	Apremilast STADA 10 mg + 20 mg + 30 mg Filmtabletten
Finland:	Apremilast STADA 30 mg kalvopäällysteiset tabletit
	Apremilast STADA 10 mg + 20 mg + 30 mg kalvopäällysteiset tabletit
France:	APREMILAST STADA 30 mg, comprimé pelliculé
	APREMILAST STADA 10 mg, comprimé pelliculé,
	APREMILAST STADA 20 mg, comprimé pelliculé,
	APREMILAST STADA 30 mg, comprimé pelliculé
Greece:	APREMILAST/STADA
Hungary:	Apremilast STADA 30mg filmtabletta
	Apremilast STADA 10mg filmtabletta
	Apremilast STADA 20mg filmtabletta
	Apremilast STADA 30mg filmtabletta
Iceland:	Apremilast STADA 30 mg filmuhúðaðar töflur
	Apremilast STADA 10 mg + 20 mg + 30 filmuhúðaðar töflur
Ireland:	Apremilast Clonmel 30 mg film-coated tablets
	Apremilast Clonmel 10 mg film-coated tablets
	Apremilast Clonmel 20 mg film-coated tablets
	Apremilast Clonmel 30 mg film-coated tablets
Italy:	Apremilast EG
Luxembourg:	Apremilast EG 30 mg comprimés pelliculés
	Apremilast EG 10 mg/20 mg/30 mg comprimés pelliculés
Malta:	Apremilast Clonmel 30 mg film-coated tablets
	Apremilast Clonmel 10 mg film-coated tablets
	Apremilast Clonmel 20 mg film-coated tablets
	Apremilast Clonmel 30 mg film-coated tablets
Netherlands:	Apremilast STADA 30 mg, filmomhulde tabletten
	Apremilast STADA 10 mg + 20 mg + 30 mg, filmomhulde tabletten
Norway:	Apremilast STADA
	Apremilast STADA
Romania:	Apremilast Stada 30 mg comprimate filmate
	Apremilast Stada 10 mg comprimate filmate
	Apremilast Stada 20 mg comprimate filmate
	Apremilast Stada 30 mg comprimate filmate

Slovakia:	Apremilast STADA 30 mg filmom obalené tablet
	Apremilast STADA 10mg filmom obalené tablet
	Apremilast STADA 20mg filmom obalené tablet
	Apremilast STADA 30mg filmom obalené tablet
Slovenia:	Apremilast STADA 30 mg filmsko obložene tablete
	Apremilast STADA 10 mg filmsko obložene tablete
	Apremilast STADA 20 mg filmsko obložene tablete
	Apremilast STADA 30 mg filmsko obložene tablete
Spain:	Apremilast STADA 30 mg comprimidos recubiertos con pelicula EFG
	Apremilast STADA 10 mg 20 mg 30 mg comprimidos recubiertos con pelicula EFG
Sweden:	Apremilast STADA 30 mg filmdragerade tabletter
	Apremilast STADA 10 mg + 20 mg + 30 filmdragerade tabletter

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