Package leaflet: Information for the patient

Apremilast STADA 30 mg, filmomhulde tabletten
Apremilast STADA 10 mg + 20 mg + 30 mg, filmomhulde tabletten
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 <Product name> is and what it is used for

What <Product name> is

<Product name> contains the active substance 'apremilast'. This belongs to a group of medicines called phosphodiesterase 4 inhibitors, which help to reduce inflammation.

What <Product name> is used for

<Product name> 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.

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 <Product name> works

Psoriatic arthritis, psoriasis and Behçet's disease are usually lifelong conditions and there is currently no cure. <Product name> 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, <Product name> 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 psoriatic arthritis, treatment with <Product name> results in an improvement in swollen and painful joints, and can improve your general physical function.

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

In Behçet's disease, treatment with <Product name> reduces the number of mouth ulcers and can stop them completely. It can also reduce the associated pain.

<Product name> has also been shown to improve the quality of life in patients with psoriasis, psoriatic arthritis or 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 <Product name>

DO NOT take <Product name>:

- 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 <Product name>.

Depression and suicidal thoughts

Tell your doctor before starting <Product name> 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 <Product name>.

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 <Product name> 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 has not been studied in children and adolescents, therefore it is not recommended for use in children and adolescents aged 17 years and under.

Other medicines and <Product name>

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 <Product name> can affect the way some other medicines work. Also some other medicines can affect the way <Product name> works.

In particular, tell your doctor or pharmacist before taking <Product name> 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

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 <Product name> in pregnancy. You should not become pregnant while taking this medicine and should use an effective method of contraception during treatment with <Product name>.
It is not known if this medicine passes into human milk. You should not use <Product name> while breast-feeding.

Driving and using machines

<Product name> has no effect on the ability to drive and use machines.

<Product name> contains lactose and sodium

<Product name> 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 <Product name>

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 <Product name>, you will receive a 'treatment initiation pack' which contains all the doses as listed in the table below.
- 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 over the first 6 days of treatment.
- The 'treatment initiation pack' will also contain enough tablets for another 8 days at the recommended dose (days 7 to 14).

- The recommended dose of <Product name> 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.
- This is a total daily dose of 60 mg. By the end of day 6 you will have reached this recommended dose.
- Once the recommended dose has been reached, you will only get the 30 mg tablet strength in your prescribed packs. You will only ever need to go through this stage of gradually increasing your dose once even if you re-start treatment.

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

People with severe kidney problems

If you have severe kidney problems then the recommended dose of <Product name> 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 <Product name>.

How and when to take <Product name>

- <Product name> 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 <Product name> 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 <Product name> than you should

If you take more <Product name> 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 <Product name>

- If you miss a dose of <Product name>, 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 <Product name>

- You should continue taking <Product name> until your doctor tells you to stop.
- Do not stop taking <Product name> 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

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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 <Product name> 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 <Product name> looks like and contents of the pack

<Product name> 10 mg, filmomhulde tabletten
Pink, oval, biconvex (8 mm in length and 4 mm in width).

<Product name> 20 mg, filmomhulde tabletten
Brown, oval, biconvex (10 mm in length and 5 mm in width).

<Product name> 30 mg, filmomhulde tabletten
Beige, oval, biconvex (13 mm in length and 6 mm in width).

Pack sizes

<Product name> 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.

<Product name> 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.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder:
STADA Arzneimittel AG
Stadastrasse 2-18

61118 Bad Vilbel
Duitsland

Fabrikant:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

STADA Arzneimittel GmbH
Muthgasse 36/2
1190 Wenen
Oostenrijk

Clonmel Healthcare Ltd.
Waterford Road
E91 D768 Clonmel, Co. Tipperary
Ierland

Centrafarm Services B.V.
Van de Reijtstraat 31-E
4814NE Breda
Nederland

In het register ingeschreven onder:

Apremilast STADA 30 mg, filmomhulde tabletten	RVG 131123
Apremilast STADA 10 mg + 20 mg + 30 mg, filmomhulde tabletten	RVG 131124

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

België, Italië, Luxemburg:	Apremilast EG
Cyprus, Denemarken, Duitsland, Finland, Frankrijk, Griekenland, Hongarije, IJsland, Nederland, Noorwegen, Oostenrijk, Roemenië, Slovenië, Slowakije, Spanje, Zweden:	Apremilast STADA
Ierland, Malta:	Apremilast Clonmel

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2024