PACKAGE LEAFLET

Package leaflet: Information for the patient

Tivlemaq® 10 mg, 20 mg, 30 mg, filmomhulde tabletten
Tivlemaq® 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 [Nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance ‘apremilast’. This belongs to a group of medicines called phosphodiesterase 4 inhibitors, which help to reduce inflammation.

What [Nationally completed name] is used for

[Nationally completed 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 [Nationally completed name] works

Psoriatic arthritis, psoriasis and Behçet's disease are usually lifelong conditions and there is currently no cure. [Nationally completed 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, [Nationally completed 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 [Nationally completed name] results in an improvement in swollen and painful joints, and can improve your general physical function.

In psoriasis, treatment with [Nationally completed name] results in a reduction in psoriatic skin plaques and other signs and symptoms of the disease.

In Behçet's disease, treatment with [Nationally completed name] reduces the number of mouth ulcers and can stop them completely. It can also reduce the associated pain.

[Nationally completed 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 [Nationally completed name]

Do not take [Nationally completed 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 [Nationally completed name].

Depression and suicidal thoughts

Tell your doctor before starting [Nationally completed 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 [Nationally completed 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 [Nationally completed 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

[Nationally completed name] 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 [Nationally completed 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 [Nationally completed name] can affect the way some other medicines work. Also some other medicines can affect the way [Nationally completed name] works.

In particular, tell your doctor or pharmacist before taking [Nationally completed 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 [Nationally completed name] in pregnancy. You should not become pregnant while taking this medicine and should use an effective method of contraception during treatment with [Nationally completed name].
It is not known if this medicine passes into human milk. You should not use [Nationally completed name] while breast- feeding.

Driving and using machines

[Nationally completed name] has no effect on the ability to drive and use machines.

[Nationally completed name] contains lactose

[Nationally completed 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.

3. How to take [Nationally completed 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 [Nationally completed 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 [Nationally completed 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 (light pink)	**Do not take a dose**	10 mg
Day 2	10 mg (light pink)	10 mg (light pink)	20 mg
Day 3	10 mg (light pink)	20 mg (light brown)	30 mg

Day 4	20 mg (light brown)	20 mg (light brown)	40 mg
Day 5	20 mg (light brown)	30 mg (pink)	50 mg
Day 6 onwards	30 mg (pink)	30 mg (pink)	60 mg

People with severe kidney problems

If you have severe kidney problems then the recommended dose of [Nationally completed 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 [Nationally completed name].

How and when to take [Nationally completed name]

- [Nationally completed name] is for oral use.
- Swallow the tablets whole, preferably with water.
- You can take the tablets either with or without food.
- Take [Nationally completed 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 [Nationally completed name] than you should

If you take more [Nationally completed 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 [Nationally completed name]

- If you miss a dose of [Nationally completed 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 [Nationally completed name]

- You should continue taking [Nationally completed name] until your doctor tells you to stop.
- Do not stop taking [Nationally completed 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 [Nationally completed 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 carton or on the blister after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use this medicine if you notice any damage or signs of tampering to the medicine packaging.

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 [Nationally completed name] contains

The active substance is apremilast.

- [Nationally completed name] 10 mg film-coated tablets: each film-coated tablet contains 10 mg of apremilast.
- [Nationally completed name] 20 mg film-coated tablets: each film-coated tablet contains 20 mg of apremilast.
- [Nationally completed name] 30 mg film-coated tablets: each film-coated tablet contains 30 mg of apremilast.

The other ingredients in the tablet core are cellulose microcrystalline, lactose monohydrate, croscarmellose sodium and magnesium stearate.

- The film-coating contains hypromellose 2910 (E464), macrogol 3350 (E1521), lactose monohydrate, titanium dioxide (E171), iron oxide red (E172).
- The 20 mg film-coated tablet also contains iron oxide yellow (E172).
- The 30 mg film-coated tablet also contains iron oxide yellow (E172) and ferrosoferric oxide (E172).

What [Nationally completed name] looks like and contents of the pack

{[Nationally completed name] 10 mg film-coated tablets}
The [Nationally completed name] 10 mg film-coated tablet is light pink, oval, unscored film coated tablet of approximately 8 mm length and 4 mm width, with “AM” engraved on one side and “10” on the other side.

{[Nationally completed name] 20 mg film-coated tablets}
The [Nationally completed name] 20 mg film-coated tablet is a light brown, oval, unscored film coated tablet approximately 10 mm length and 5 mm width, with “AM” engraved on one side and “20” on the other side.

{[Nationally completed name] 30 mg film-coated tablets}
The [Nationally completed name] 30 mg film-coated tablet is pink, oval, unscored film coated tablet approximately 11 mm length and 6 mm width, with "AM" engraved on one side and "30" on the other side.

Pack sizes
- The treatment initiation pack contains blisters with 27 film-coated tablets or unit-dose blisters with 27x1 film-coated tablets: 4 x 10 mg tablets, 4 x 20 mg tablets and 19 x 30 mg tablets.
- The maintenance pack contains blisters with 56, 168, 196 film-coated tablets of 30 mg or unit-dose blisters with 56x1, 168x1 and 196x1 film-coated tablets of 30 mg.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

Fabrikant
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
39179 Barleben
Duitsland

In het register ingeschreven onder:

RVG 131163
RVG 131164

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

Nederland:	Tivlemaq 10 mg, 20 mg, 30 mg filmomhulde tabletten Tivlemaq 30 mg, filmomhulde tabletten
Oostenrijk:	Tivlemaq 10 mg, 20 mg, 30 mg – Filmtabletten Starterpackung Tivlemaq 30 mg – Filmtabletten
Bulgarije:	ТИВЛЕМАК 10 mg, 20 mg, 30 mg филмирани таблетки ТИВЛЕМАК 30 mg филмирани таблетки
Kroatië:	Tivlemaq 10 mg, 20 mg ,30 mg filmom obložene tablete Tivlemaq 30 mg filmom obložene tablete

Polen:	TIVLEMAQ
Slovenië:	Tivlemaq 10 mg, 20 mg, 30 mg filmsko obložene tablete (pakiranje za začetek zdravljenja) Tivlemaq 30 mg filmsko obložene tablete
Slowakije:	TIVLEMAQ 10 mg, 20 mg, 30 mg TIVLEMAQ 30 mg

Deze bijsluiter is voor het laatst goedgekeurd in januari 2025