Package leaflet: Information for the patient

Apremilast Krka 10 mg film-coated tablets
Apremilast Krka 20 mg film-coated tablets
Apremilast Krka 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 Krka is and what it is used for
2. What you need to know before you take Apremilast Krka
3. How to take Apremilast Krka
4. Possible side effects
5. How to store Apremilast Krka
6. Contents of the pack and other information

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

What Apremilast Krka is

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

What Apremilast Krka is used for

Apremilast Krka 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 Krka 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 Krka.

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 Krka works

Psoriatic arthritis, psoriasis and Behçet's disease are usually lifelong conditions and there is currently no cure. Apremilast Krka 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 Krka 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 Krka 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 Krka 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 Krka reduces the number of mouth ulcers and can stop themcompletely. It can also reduce the associated pain.

Apremilast Krka 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 andother factors should be less than it was before.

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

Do not take Apremilast Krka

- 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 Krka.

Depression and suicidal thoughts

Tell your doctor before starting Apremilast Krka if you have depression which is getting worse with thoughts ofsuicide.

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 Krka.

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 Krka 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 Krka 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 Krka 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 Krka

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

In particular, tell your doctor or pharmacist before taking Apremilast Krka if you are taking any of the followingmedicines:

- 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 Krka 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, askyour doctor or pharmacist for advice before taking this medicine.
There is little information about the effects of Apremilast Krka in pregnancy. You should not become pregnant while taking this medicine and should use an effective method of contraception during treatment withApremilast Krka.
It is not known if this medicine passes into human milk. You should not use Apremilast Krka while breast-feeding.

Driving and using machines

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

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

3. How to take Apremilast Krka

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

How much to take

- When you first start taking Apremilast Krka, 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.
- Once 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 Krka 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 (orange brown)	30 mg
Day 4	20 mg (orange brown)	20 mg (orange brown)	40 mg
Day 5	20 mg (orange brown)	30 mg (light brownish violet)	50 mg
Day 6 onwards	30 mg (light brownish violet)	30 mg (light brownish violet)	60 mg

Children and adolescents 6 years of age and older
- The Apremilast Krka dose will be based on body weight.

For patients who weigh from 20 kg to less than 50 kg *: The recommended dose of Apremilast Krka 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 (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 (orange brown)	30 mg
Day 4	20 mg (orange brown)	20 mg (orange brown)	40 mg
Day 5	20 mg (orange brown)	20 mg (orange brown)	40 mg
Day 6 onwards	20 mg (orange brown)	20 mg (orange brown)	40 mg

* There are no dosage packages for Apremilast Krka 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 Krka; other apremilast products offering these dosage packages should be used instead.

For patients who weigh at least 50 kg: The recommended dose of Apremilast Krka 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 (orange brown)	30 mg
Day 4	20 mg (orange brown)	20 mg (orange brown)	40 mg
Day 5	20 mg (orange brown)	30 mg (light brownish violet)	50 mg
Day 6 onwards	30 mg (light brownish violet)	30 mg (light brownish violet)	60 mg

Patients with severe kidney problems

If you are an adult with severe kidney problems, then the recommended dose of Apremilast Krka 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 Krka is 30 mg once a day (morning dose) for patients who weigh at least 50 kg and 20 mg once a day (morning dose) for children who weigh 20 kg to less than 50 kg.

Your doctor will talk to you about how to increase your dose when you first start taking Apremilast Krka. 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 Krka

- Apremilast Krka is for oral use.
- Swallow the tablets whole, preferably with water.
- You can take the tablets either with or without food.
- Take Apremilast Krka 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 Krka than you should

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

If you forget to take Apremilast Krka

- If you miss a dose of Apremilast Krka, 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 Krka

- You should continue taking Apremilast Krka until your doctor tells you to stop.
- Do not stop taking Apremilast Krka 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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Apremilast Krka

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 packaging 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 Krka contains
- The active substance is apremilast. Each film-coated tablet contains 10 mg, 20 mg or 30 mg apremilast.
- The other ingredients (excipients) are:
  Tablet core: mannitol (E421), microcrystalline cellulose, croscarmellose sodium (See section 2 "Apremilast Krka contains sodium") and magnesium stearate (E470b).
  Film coating: poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171), talc, red iron oxide (E172), yellow iron oxide (E172) - *only for 20 mg and 30 mg* and black iron oxide (E172) - *only for 30 mg*.

What Apremilast Krka looks like and contents of the pack

Apremilast Krka 10 mg film-coated tablets
Film-coated tablets (tablets) are pink, round, biconvex, marked with 10 on one side of the tablet. Tablet dimension: diameter approx. 6 mm.

Apremilast Krka 20 mg film-coated tablets
Film-coated tablets (tablets) are orange brown, round, biconvex marked with 20 on one side of the tablet. Tablet dimension: diameter approx. 8 mm.

Apremilast Krka 30 mg film-coated tablets
Film-coated tablets (tablets) are light brownish violet, round, biconvex, marked with 30 on one side of the tablet. Tablet dimension: diameter approx. 10 mm.

- Apremilast Krka 30 mg film-coated tablets is available in:
- packs containing 14, 56, 168 or 196 film-coated tablets, in a blister.

- Treatment initiation pack:
Each pack of 27 film-coated tablets contains:
- 4 film-coated tablets of Apremilast Krka 10 mg
- 4 film-coated tablets of Apremilast Krka 20 mg
- 19 film-coated tablets of Apremilast Krka 30 mg

Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Finaland, Italy, Ireland, Slovakia, Spain, Sweden	Apremilast Krka
Germany	Apremilast TAD

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