STATE INSTITUTE FOR DRUG CONTROL
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Summary Public Assessment Report

Generics

Apremilast Krka d.d.
Apremilast Krka
Apremilast HCS

apremilast

SK/H/0306/001-002/DC
SK/H/0307/001-002/DC
SK/H/0309/001-002/DC

Date: 09/2024

Summary Public Assessment Report

Generics

Apremilast Krka d.d./Apremilast Krka/Apremilast HCS

(for the purpose of this report name Apremilast Krka is used)

Apremilast, film coated tablets, 10 mg+20 mg+30 mg (treatment initiation pack) and 30 mg

This is a summary of the public assessment report (PAR) for Apremilast Krka. It explains how Apremilast Krka was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Apremilast Krka.

For practical information about using Apremilast Krka, patients should read the package leaflet or contact their doctor or pharmacist.

What is Apremilast Krka and what is it used for?

Apremilast Krka is a 'generic medicine'. This means that Apremilast Krka is similar to a 'reference medicine' already authorised in the European Union (EU) called Otezla.

Apremilast Krka is used to treat adults with the following conditions:
Active psoriatic arthritis, if another type of medicine called 'Disease-Modifying Antirheumatic Drugs' (DMARDs) cannot be used or when it doesn't work.
Moderate to severe chronic plaque psoriasis, if the use one of the following treatments cannot be used or when they don't 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.

How does Apremilast Krka work?

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

In psoriasis, treatment with Apremilast Krka results in a reduction in psoriatic skin plaques and other signs andsymptoms of the disease.

In 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 patients with psoriasis, psoriatic arthritis or Behçet's disease. This means that the impact of your condition on daily activities, relationships andother factors should be less than it was before.

How is Apremilast Krka used?

The pharmaceutical form of Apremilast Krka is film-coated tablet and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Treatment starts with a 'treatment initiation pack' at a lower dose and will gradually be increased over the first 6 days of treatment. By the end of day 6 recommended dose will be reached.

The recommended dose of Apremilast Krka 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. The total daily dose is 60 mg.

The medicine can only be obtained with a prescription.

What benefits of Apremilast Krka have been shown in studies?

Because Apremilast Krka is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Otezla. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

Applicant submitted three identical marketing authorisation applications (duplicates), which were approved under the names of Apremilast Krka d.d./Apremilast Krka/Apremilast HCS.

What are the possible side effects of Apremilast Krka?

Because Apremilast Krka is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Apremilast Krka approved?

It was concluded that, in accordance with EU requirements, Apremilast Krka has been shown to have comparable quality and to be bioequivalent to reference medicine. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Otezla, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Apremilast Krka?

A risk management plan has been developed to ensure that Apremilast Krka is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Apremilast Krka, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Apremilast Krka

The marketing authorisation for Apremilast Krka d.d./Apremilast Krka/Apremilast HCS was granted on 28.08.2024.

The full PAR for Apremilast Krka can be found on the website https://www.sukl.sk/. For more information about treatment with Apremilast Krka, read the package leaflet (*sukl.sk*) or contact your doctor or pharmacist.

This summary was last updated in 09.2024.