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Otezla (*apremilast*)

An overview of Otezla and why it is authorised in the EU

What is Otezla and what is it used for?

Otezla is a medicine used to treat adults with:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in patients who have not responded to, or cannot use, other systemic (affecting the whole body) treatments for psoriasis, such as ciclosporin, methotrexate or PUVA (psoralen ultraviolet A). PUVA is a type of treatment where the patient receives a medicine containing a compound called a 'psoralen' before being exposed to ultraviolet light;
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in patients who cannot take or have not responded well enough to other treatments called disease-modifying antirheumatic drugs (DMARDs). Otezla may be used alone or combined with other DMARDs;
- ulcers in the mouth caused by Behçet's disease, an inflammatory disease that may affect many parts of the body;

Otezla is also used to treat children aged 6 years and older weighing at least 20 kg with moderate to severe plaque psoriasis who can receive systemic treatments.

Otezla contains the active substance apremilast.

How is Otezla used?

Otezla can only be obtained with a prescription and treatment should be started by a doctor experienced in the diagnosis and treatment of psoriasis, psoriatic arthritis or Behçet's disease.

The medicine is available as tablets to be taken by mouth twice a day, 12 hours apart. Response to treatment should be evaluated regularly and use of Otezla should be reconsidered if there is no improvement after six months for psoriasis and psoriatic arthritis, and 3 months for Behçet's disease.

For more information about using Otezla, see the package leaflet or contact your doctor or pharmacist.

How does Otezla work?

The active substance in Otezla, apremilast, blocks the action of an enzyme inside cells called phosphodiesterase 4 (PDE4). This enzyme plays a role in triggering the production of messenger

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molecules of the immune system (the body's natural defences) called cytokines. Cytokines are involved in the inflammation and other processes that cause psoriasis, psoriatic arthritis and Behçet's disease. By blocking PDE4, apremilast lowers the level of these cytokines in the body, thereby reducing inflammation and relieving symptoms of these diseases.

What benefits of Otezla have been shown in studies?

Psoriasis

In psoriasis, Otezla has been investigated in 2 main studies involving a total of 1,257 patients with moderate to severe plaque psoriasis, in which treatment with Otezla was compared with placebo (a dummy treatment). The main measure of effectiveness in both studies was the proportion of patients who 'responded' to treatment after 16 weeks. Response to treatment was defined as patients having a 75% or more reduction in a symptom score known as Psoriasis Area Severity Index (PASI-75). Of the patients given Otezla in these two studies, 33% (168 of 562) and 29% (79 of 274) responded to treatment. This compared with 5% (15 of 282) and 6% (8 of 137) given placebo.

Otezla has also been investigated in a study involving 245 children aged 6 to 17 years and weighing at least 20 kg with moderate to severe plaque psoriasis, in which treatment with Otezla was compared with placebo. The study looked at an improvement in symptoms by measuring the severity and extent of skin lesions using the sPGA score. After 16 weeks of treatment, around 33% of patients (54 out of 163) given Otezla achieved a sPGA score of 0 or 1 (indicating skin clear or almost clear of lesions, respectively), along with an improvement of at least 2 points in their score. This compared with about 11% of patients (9 out of 82) given placebo.

Psoriatic arthritis

In psoriatic arthritis, Otezla has been compared with placebo in 3 main studies, involving a total of 1,493 patients with active disease despite prior treatment. Patients who were already taking other so-called 'small-molecule DMARDs', such as the medicine methotrexate continued this treatment during the study. The main measure of effectiveness was a 20% improvement in a score measuring symptoms such as tender and swollen joints (ACR-20) after 16 weeks of treatment. This was achieved in between 32 and 41% of patients given the approved dose of Otezla in the three studies, compared with 18 to 19% of those given placebo. Benefit was seen both in patients taking Otezla alone and those also taking other DMARDs.

For both psoriasis and psoriatic arthritis, there was evidence that the benefits were maintained when treatment was extended to 32 and 52 weeks, respectively.

Behçet's disease

In Behçet's disease, a study in 207 patients with mouth ulcers compared Otezla with placebo. After 3 months of treatment, 53% of patients given Otezla no longer had mouth ulcers, compared with 22% of those given placebo.

What are the risks associated with Otezla?

For the full list of all side effects and restrictions with Otezla, see the package leaflet.

The most common side effects with Otezla in adults with psoriasis or psoriatic arthritis (which may affect more than 1 in 10 people) include diarrhoea, nausea (feeling sick), upper respiratory tract infection (nose and throat infection) and headaches. In children with psoriasis, side effects with Otezla are similar to those seen in adults with psoriasis.

In adults with Behçet's disease, the most common side effects with Otezla (which may affect more than 1 in 10 people) include diarrhoea, nausea, headache, upper respiratory tract infection, upper abdominal (belly) pain, vomiting and back pain.

Otezla must not be used during pregnancy, and women who can become pregnant should use effective contraception during treatment.

Why is Otezla authorised in the EU?

The European Medicines Agency decided that Otezla's benefits are greater than its risks and it can be authorised for use in the EU.

Studies showed that Otezla reduces the symptoms of plaque psoriasis and psoriatic arthritis. In these studies, the medicine had not been compared with other authorised treatments, and for psoriatic arthritis, X-ray evidence of an effect on the progression of the disease was lacking. However, the medicine can be taken by mouth and has mostly mild to moderate side effects, which may make it more acceptable to patients.

With respect to Behçet's disease, Otezla was shown to be effective at reducing the number of patients' mouth ulcers, which are common in patients with this condition and can be painful and difficult to treat.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Otezla have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Otezla are continuously monitored. Side effects reported with Otezla are carefully evaluated and any necessary action taken to protect patients.

Other information about Otezla

Otezla received a marketing authorisation valid throughout the EU on on 15 January 2015.

Further information on Otezla can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/otezla.

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