



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EPAR summary for the public

Otezla

apremilast

This is a summary of the European public assessment report (EPAR) for Otezla. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Otezla.

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

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 who have not responded well enough to other treatments called disease-modifying antirheumatic drugs (DMARDs). Otezla may be used alone or combined with other DMARDs.

Otezla contains the active substance apremilast.

How is Otezla used?

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



The medicine is available as tablets (10, 20 and 30 mg). Treatment is started with a dose of 10 mg on day 1 and gradually increased over a week to the recommended dose of 30 mg twice a day. Lower doses should be given to patients with severe impairment of kidney function. Response to treatment should be evaluated regularly and use of Otezla should be reconsidered if there is no improvement after six months.

For further information, see the package leaflet.

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 molecules in the immune system (the body's natural defences) called cytokines, which are involved in the inflammation and other processes that cause psoriasis and psoriatic arthritis. By blocking PDE4, apremilast reduces the level of these cytokines in the body, and so reduces the inflammation and other symptoms of psoriasis and psoriatic arthritis.

What benefits of Otezla have been shown in studies?

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.

For psoriatic arthritis, Otezla has been compared with placebo in 3 main studies, involving 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 benefit there was evidence of maintained benefit when treatment was extended (to 32 and 52 weeks respectively).

What are the risks associated with Otezla?

The most common side effects with Otezla (which may affect more than 1 in 10 people) are effects on the digestive system such as diarrhoea and nausea (feeling sick). These usually occur within the first two weeks of treatment, and get better within 4 weeks. The other common side effects (which may affect up to 1 in 10 people) are upper respiratory tract infections (colds) and headaches or tension headaches.

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

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

Why is Otezla approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Otezla's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that benefit had been shown in psoriasis and psoriatic arthritis. Although the medicine had not been compared with other authorised treatments, and for psoriatic arthritis X-ray evidence of an effect on the progress of the disease was not available, the mostly mild or moderate side effects and the fact that the medicine could be taken by mouth might make it more acceptable to patients. The Committee therefore considered that it was useful as a second-line treatment in patients who do not respond to or cannot use the first-line treatments.

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

A risk management plan has been developed to ensure that Otezla 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 Otezla, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the [summary of the risk management plan](#).

Other information about Otezla

The European Commission granted a marketing authorisation valid throughout the European Union for Otezla on 15 January 2015.

The full EPAR and risk management plan summary for Otezla can be found on the Agency's website: ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Otezla, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.