

Otezla (apremilast)

What is it?

Otezla (also known by its generic name apremilast) is an oral medication approved in March 2014 by the U.S. Food and Drug Administration (FDA) for the treatment of active psoriatic arthritis in adults. In September 2014, it was approved for moderate to severe plaque psoriasis. Otezla is available by prescription.

How does it work?

Otezla treats psoriasis and psoriatic arthritis by regulating inflammation within immune cells. It inhibits an enzyme known as phosphodiesterase 4, or PDE4. PDE4 controls much of the inflammatory action within the cell, which can affect the level of inflammation associated with psoriatic disease.

By helping to control inflammation in this way, Otezla improves joint tenderness and swelling in people with psoriatic arthritis, and redness and scaliness of plaque psoriasis.

Who can take it?

Otezla is prescribed for adults with active psoriatic arthritis. It is also prescribed for people with moderate to severe plaque psoriasis.

Who should not take it?

The safety and effectiveness of Otezla in people under 18 years of age has not been established. Additionally, the dose of Otezla should be modified or reduced in people with severe renal impairment. Nursing women should use caution when taking Otezla. People with a known severe allergic reaction to this treatment or its components should not take Otezla.

How is it used?

Otezla is available as a 30-milligram (mg) tablet. The first five days of treatment is a start period, where the dosage will gradually increase over five days until the recommended dose of 30 milligrams twice daily is reached. Otezla is designed to be taken continuously to maintain improvement.

Can it be used with other treatments?

Yes, Otezla can be used with other treatments. In clinical trials, no significant impacts were observed when 30 mg of Otezla was taken with either oral birth control, ketoconazole (antifungal medication), or methotrexate. Taking a CYP450 inducer treatment (such as rifampin, a medication used to treat tuberculosis) at the same time as Otezla may reduce efficacy.

Effectiveness

Psoriasis disease severity is determined by assessing the degree of redness, shedding, plaque thickness and affected body surface area, degree of itching, and the impact of psoriasis on quality of life. In clinical trials, about 31 percent of the individuals taking Otezla experienced a 75 percent improvement in the severity of their psoriasis after four months.

SIDE EFFECTS

In clinical trials, the most common side effects of Otezla included:

- Diarrhea
- Nausea
- Headache

Generally, these side effects were mild and did not cause patients to stop taking Otezla. They can occur during the first two weeks of treatment and tend to lessen with continued treatment.

In clinical trials, about 38 percent of patients saw a 20-percent improvement in arthritis severity scores after one 16-week course. Arthritis severity scores are usually determined by examining swelling in and around the joints and taking into consideration joint tenderness, pain, physical function and morning stiffness.

Risks

In clinical trials, the most common side effects were diarrhea, nausea and headache, which occurred in the first two weeks and tended to lessen with continued treatment.

In clinical trials, approximately 4.6 percent of the people taking Otezla for psoriatic arthritis discontinued treatment due to an adverse reaction. Approximately 6.1 percent of the people taking Otezla for psoriasis discontinued treatment due to an adverse reaction.

In clinical trials, 10 to 12 percent of people taking Otezla reported unexplained weight loss of 5 to 10 percent during their trial period. It is recommended that people taking Otezla have their weight monitored regularly.

For detailed information on side effects and safety, talk to your doctor.

Patient assistance information

Otezla SupportPlus™, a patient assistance program through Celgene Corporation, provides medication savings and additional support for people taking Otezla. For more information, call 1-844-4OTEZLA (1-844-468-3952) or visit **www.OTEZLA.com**.