European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

RAPTIVA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Raptiva?
Raptiva is a powder and solvent that are made up into a solution for injection. It contains the active substance efalizumab (100 mg/ml).

What is Raptiva used for?
Raptiva is used for the treatment of adults with moderate to severe chronic (long-term) plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in patients who have failed to respond to or cannot take other systemic (whole-body) treatments for psoriasis, including ciclosporin, methotrexate and 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.
The medicine can only be obtained with a prescription.

How is Raptiva used?
Raptiva treatment should be initiated by a doctor who specialises in dermatology (the treatment of skin conditions). It is given as a 12-week course, with a first dose of 0.7 mg per kilogram body weight followed by weekly injections of 1.0 mg/kg. Raptiva is given by injection under the skin. The maximum single dose is 200 mg. Therapy should only be continued in patients who have responded to treatment. Patients may inject themselves once they have been trained, if their doctor thinks that this is appropriate. Raptiva should be used with caution in patients who have problems with their liver or kidneys.

How does Raptiva work?
The active substance in Raptiva, efalizumab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and bind to a specific structure (called an antigen) that is found on the surface of cells in the body. Efalizumab has been designed to bind to part of a protein called LFA-1 on the surface of lymphocytes, a type of white blood cell that is involved in the inflammation process. As LFA-1 is important in helping the lymphocytes to stick to cells in the skin, efalizumab reduces the inflammation in the skin that causes psoriasis. This improves the symptoms of the disease.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

How has Raptiva been studied?
Raptiva has been studied in five main studies involving over 3,000 patients with moderate to severe plaque psoriasis. The studies included patients who had not taken other treatments for psoriasis in the past, as well as those who had taken other treatments. In the fifth study, 526 of the 793 patients were 'high need', since they had failed to respond to or could not take other systemic treatments. In all studies, the effectiveness of Raptiva was compared with that of placebo (a dummy treatment). The main measure of effectiveness was the proportion of patients who 'responded' to treatment after 12 weeks, meaning that symptom scores improved by 75% or more.

What benefit has Raptiva shown during the studies?
Raptiva was more effective than placebo at improving the symptoms of psoriasis. Looking at the results of the first four studies taken together, 320 (26%) of the 1,213 patients receiving 1.0 mg/kg Raptiva per week responded to treatment, compared with 25 (4%) of the 715 receiving placebo. The results were similar in those who had and those who had not taken systemic treatments for psoriasis before.
In the fifth study, overall, 166 (31%) of the 529 patients receiving Raptiva responded to treatment, compared with 11 (4%) of the 264 receiving placebo. Looking only at the 'high need' patients in this study, 30% of those receiving Raptiva responded to treatment, compared with 3% of those receiving placebo.

What is the risk associated with Raptiva?
The most common side effects with Raptiva (seen in more than 1 patient in 10) are mild to moderate flu-like symptoms including headache, fever, chills, nausea (feeling sick), myalgia (muscle pain), and leucocytosis and lymphocytosis (increased white blood cell counts). For the full list of all side effects reported with Raptiva, see the Package Leaflet.
Raptiva should not be used in people who may be hypersensitive (allergic) to efalizumab or any of the other ingredients. It should also not be used in patients who have had cancer, who have active tuberculosis or another severe infection, who have other types of psoriasis, or who have low levels of immunity.

Why has Raptiva been approved?
The Committee for Medicinal products for Human Use (CHMP) noted that psoriasis was more severe in 'high-need' patients, and that the effectiveness of Raptiva is relevant for these patients. Therefore, the Committee decided that Raptiva's benefits are greater than its risks for the treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contra-indication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and PUVA. The Committee recommended that Raptiva be given marketing authorisation.

Other information about Raptiva:
The European Commission granted a marketing authorisation valid throughout the European Union for Raptiva to Serono Europe Ltd. on 20 September 2004.

The full EPAR for Raptiva can be found here.

This summary was last updated in 10-2007.