European Medicines Agency

EMEA/H/C/482

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TRUDEXA

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).

Medicinal Product no longer authorised

What is Trudexa?

Trudexa is a medicine containing the active substance adalimumab. It is available as a solution for injection in a vial, pre-filled syringe or pre-filled pen, all containing 40 mg of adalimumab.

What is Trudexa used for?

Trudexa is an anti-inflammatory medicine. It is used to treat adults with the following diseases:

- rheumatoid arthritis (an immune system disease causing inflammation of the joints). Trudexa is used in combination with methotrexate (a medicine that acts on the immune system) in patients with moderate or severe disease who have not responded adequately to other treatments, or patients with severe disease who have not taken methotrexate before. Trudexa can be used alone if the patient cannot take methotrexate.
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints) in patients who have not responded adequately to other treatments,
- severe ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine) in patients who have not responded adequately to other treatments.

For more information, see the Package Leaflet.
The medicine can only be obtained with a prescription.

How is Trudexa used?

Treatment with Trudexa must be initiated and supervised by a doctor who has experience in the treatment of the diseases that Trudexa is used to treat. The recommended dose of Trudexa is 40 mg given every 2 weeks as a single subcutaneous injection (under the skin). Some patients with rheumatoid arthritis who are taking Trudexa without methotrexate may benefit from taking this dose every week. After training, patients may inject themselves with Trudexa if their doctor agrees. Patients who take Trudexa must be given the special alert card that summarises the safety information about the medicine.

How does Trudexa work?

The active substance in Trudexa, adalimumab, 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 in the body. Adalimumab has been designed to bind to a chemical messenger in the body called tumour necrosis factor (TNF). This messenger is involved in causing inflammation

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and is found at high levels in patients with the diseases that Trudexa is used to treat. By blocking TNF, adalimumab improves the inflammation and other symptoms of the diseases.

How has Trudexa been studied?
Trudexa has been studied in five studies including almost 2,900 patients with moderate to severe rheumatoid arthritis. In four of these studies (involving over 2,000 patients), the effectiveness of Trudexa, alone or as an as add-on to other anti-inflammatory medicines, including methotrexate, was compared with that of a placebo (a dummy treatment) in patients who generally had taken anti-arthritis medicines in the past. The fifth study included 799 patients, none of whom had taken methotrexate in the past, and compared the combination of Trudexa and methotrexate to methotrexate or Trudexa alone. In all five studies, the main measure of effectiveness was the change in symptoms after 6 months to a year of treatment.
For psoriatic arthritis, Trudexa was compared to placebo in two studies including 413 patients. The medicines were taken alone or in combination with another anti-inflammatory medicine such as methotrexate. For ankylosing spondylitis, Trudexa and placebo as an add-on to existing treatment were compared in two studies involving 397 patients. For both diseases, the patients had had an inadequate response to previous therapy, and the main measure of effectiveness was the change in symptoms after 12 weeks of treatment.

What benefit has Trudexa shown during the studies?
In rheumatoid arthritis, Trudexa was more effective than placebo in reducing symptoms. The greatest reductions were seen in the studies examining Trudexa as an add-on to methotrexate: in the two studies taken together, around two thirds of the patients adding 40 mg Trudexa every 2 weeks had at least a 20% reduction in symptoms after 6 months, compared to a quarter of those adding placebo. Patients adding Trudexa also had less joint damage and experienced less reduction in physical function than those adding placebo after a year of treatment. In the patients who had not taken methotrexate before, more patients taking Trudexa and methotrexate had a 50% reduction in symptoms than those taking methotrexate alone over a year of treatment (62% and 46%, respectively). For the other two diseases, Trudexa produced a greater improvement in symptoms than placebo.

What is the risk associated with Trudexa?
In studies of Trudexa, the most common side effects (seen in more than 1 patient in 10) were upper respiratory infection (colds) and injection site reactions (including pain, swelling, redness or pruritus [itching]). Due to an increased risk of infection, patients must be monitored closely for infections, including tuberculosis, during and for up to 5 months after treatment with Trudexa. For the full list of all side effects reported with Trudexa, see the Package Leaflet.
Trudexa should not be used in people who may be hypersensitive (allergic) to adalimumab or any of the other ingredients. Trudexa should not be used in patients with tuberculosis, other severe infections, or moderate or severe heart failure.

Why has Trudexa been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that Trudexa's benefits are greater than its risks for treatment of moderate to severe rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis in adults when other treatments have been inadequate. In rheumatoid arthritis, Trudexa has been shown to reduce the rate at which joint damage gets worse and to improve physical function, when given in combination with methotrexate. The committee recommended that Trudexa be given marketing authorisation.

Other information about Trudexa:
The European Commission granted a marketing authorisation valid throughout the European Union for Trudexa to Abbott Laboratories Ltd. on 1 September 2003.

The full EPAR for Trudexa can be found here.

This summary was last updated in 03-2007.

Medicinal Product no longer authorised