EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2018
EMA/CHMP/241919/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Halimatoz

adalimumab

On 31 May 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Halimatoz, intended for certain inflammatory and autoimmune disorders (full list below). The applicant for this medicinal product is Sandoz GmbH.

Halimatoz will be available as a 40-mg solution for injection. The active substance of Halimatoz is adalimumab, a tumour necrosis factor alpha (TNFα) inhibitor (ATC code: L04AB04). Adalimumab binds to TNF and blocks its interaction with the p55 and p75 cell-surface TNF receptors. Adalimumab also modulates biological responses that are induced or regulated by TNFα, including changes in the levels of adhesion molecules responsible for leucocyte migration (ELAM-1, VCAM-1, and ICAM-1).

Halimatoz is a biosimilar medicinal product. It is highly similar to the reference product Humira (adalimumab), which was authorised in the EU on 8 September 2003. Data show that Halimatoz has comparable quality, safety and efficacy to Humira (adalimumab). More information on biosimilar medicines can be found here.

The full indication is:

"Rheumatoid arthritis

Halimatoz in combination with methotrexate, is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

Halimatoz can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Adalimumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.

Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis

Halimatoz in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Halimatoz can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate (for the efficacy in monotherapy see section 5.1 of the SmPC). Adalimumab has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis

Halimatoz is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy (see section 5.1 of the SmPC).

Axial spondyloarthritis

Ankylosing spondylitis (AS)

Halimatoz is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

Axial spondyloarthritis without radiographic evidence of AS

Halimatoz is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and / or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

Psoriatic arthritis

Halimatoz is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.

Adalimumab has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease (see section 5.1 of the SmPC) and to improve physical function.

Psoriasis

Halimatoz is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.

Paediatric plaque psoriasis

Halimatoz is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.

Hidradenitis suppurativa (HS)

Halimatoz is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults and adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy (see sections 5.1 and 5.2 of the SmPC).

Uveitis

Halimatoz is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.

Paediatric uveitis

Halimatoz is indicated for the treatment of paediatric chronic non-infectious anterior uveitis in patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate."

Halimatoz treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Halimatoz is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.