



31 May 2018
EMA/CHMP/241971/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Hefiya

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 Hefiya, intended for certain inflammatory and autoimmune disorders (full list below). The applicant for this medicinal product is Sandoz GmbH.

Hefiya will be available as a 40-mg solution for injection. The active substance of Hefiya is adalimumab, a tumour necrosis factor alpha (TNF α) 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 TNF α , including changes in the levels of adhesion molecules responsible for leucocyte migration (ELAM-1, VCAM-1, and ICAM-1).

Hefiya 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 Hefiya has comparable quality, safety and efficacy to Humira (adalimumab). More information on biosimilar medicines can be found [here](#).

The full indication is:

“Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis

Hefiya 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). Hefiya 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.

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



Enthesitis-related arthritis

Hefiya 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)

Hefiya 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

Hefiya 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

Hefiya 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

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

Paediatric plaque psoriasis

Hefiya 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)

Hefiya 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

Hefiya 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

Hefiya 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."

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