22 May 2025
EMA/CHMP/144927/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Riulvy

tegomil fumarate

On 22 May 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Riulvy, intended for the treatment of adults and children from 13 years of age with relapsing remitting multiple sclerosis. The applicant for this medicinal product is Neuraxpharm Pharmaceuticals, S.L.

Riulvy will be available as 174 mg and 348 mg gastro-resistant hard capsules. The active substance of Riulvy is tegomil fumarate, an immunosuppressant (ATC code: L04AX10). The mechanism of action of tegomil fumarate is not fully understood but it is thought to act via its main active metabolite monomethyl fumarate. This metabolite activates the Nrf2 transcriptional pathway, which reduces inflammation and modulates the activity of immune cells, thereby protecting the cells of the central nervous system from damage.

The benefits of Riulvy are its ability to reduce the number of relapses in patients with relapsing remitting multiple sclerosis. The most common side effects with Riulvy include flushing and gastrointestinal events (e.g. diarrhoea, nausea and abdominal pain).

Riulvy is a hybrid medicine[2] of Tecfidera, which has been authorised in the EU since 30 January 2014. Riulvy contains a different active substance but acts via the same active metabolite as Tecfidera, monomethyl fumarate. Studies have demonstrated the satisfactory quality of Riulvy, and its bioequivalence to the reference product Tecfidera.

The full indication is:

> RIULVY is indicated for the treatment of adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis (RRMS).

Treatment with Riulvy should be initiated under the supervision of a physician experienced in the treatment of multiple sclerosis.

Detailed recommendations for the use of this product will be described in the summary of product

[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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.