16 September 2021
EMA/CHMP/504133/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Byannli[2]

paliperidone

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Paliperidone Janssen-Cilag International, which will now be known as Byannli. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V..

Byannli will be available as prolonged-release suspension for injection (700 or 1,000 mg) for 6-monthly administration. The active substance of Byannli is paliperidone, a psycholeptic antipsychotic (ATC code: N05AX13).

The full indication is:

> **Byannli, a 6-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly or 3-monthly paliperidone palmitate injectable products (see section 5.1).**

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

[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] Formerly Paliperidone Janssen-Cilag International

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