1 April 2016
EMA/CHMP/237035/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Trevicta

paliperidone

On 1 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation of the medicinal product previously known as Paliperidone Janssen and now to be known as Trevicta. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

Trevicta will now be available as 175-mg, 263-mg, 350-mg and 525-mg prolonged-release suspensions for injection. All previous strengths have been withdrawn.

Furthermore, the CHMP adopted a change to the existing indication as follows[2]:

"~~Paliperidone Janssen~~**Trevicta, a 3-monthly injection**, is indicated for **the** maintenance treatment of schizophrenia in adult patients ~~stabilised with paliperidone or risperidone~~ **who are clinically stable on 1-monthly paliperidone palmitate injectable product.**

~~In selected adult patients with schizophrenia and previous responsiveness to oral paliperidone or risperidone, Paliperidone Janssen may be used without prior stabilisation with oral treatment if psychotic symptoms are mild to moderate and a long-acting injectable treatment is needed.~~"

For information, the full indication for Trevicta will be as follows:

"Trevicta, a 3-monthly injection, is indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product (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] New text in bold, removed text as strikethrough

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