15 December 2016
EMA/CHMP/734936/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Votubia

everolimus

On 15 December 2016, 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 Votubia. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted a new indication for the 2mg, 3mg, and 5mg dispersible tablets as follows:

> "Votubia is indicated as adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC)".

For information, the full indications for Votubia dispersible tablets will be as follows[2]:

> "**Refractory seizures associated with tuberous sclerosis complex (TSC)**
>
> **Votubia is indicated as adjunctive treatment of patients aged 2 years and older whose refractory partial-onset seizures, with or without secondary generalisation, are associated with tuberous sclerosis complex (TSC).**
>
> **Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC)**
>
> Votubia is indicated for the treatment of patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery.
>
> The evidence is based on analysis of change in SEGA volume. Further clinical benefit, such as improvement in disease-related symptoms, has not been demonstrated."

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

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