



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2011
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Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Votubia everolimus

On 23 June 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product **Votubia**, 2.5mg, 5mg, 10mg, tablet, intended for the treatment of patients aged 3 years and older with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) who require therapeutic intervention but are not amenable to surgery. **Votubia** was designated as an orphan medicinal product on 4 August 2010. The applicant for this medicinal product is Novartis Europharm Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of **Votubia** is everolimus, a protein kinase inhibitors (L01XE10), which inhibits a signalling pathway associated with the translation and synthesis of proteins and as a consequence, inhibits the growth and proliferation of tumour cells.

The benefit with **Votubia** is its ability to reduce primary tumour volume in SEGA patients. The most common side effects are stomatitis, upper respiratory tract infection, sinusitis, otitis media, pyrexia, and acneiform dermatitis.

A pharmacovigilance plan for **Votubia** will be implemented as part of the marketing authorisation.

The approved indication is:

“**Votubia** is indicated for the treatment of patients aged 3 years and older 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.” It is proposed that treatment with **Votubia** should be initiated by a physician experienced in the treatment of patients with TSC and therapeutic drug monitoring.

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.



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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Votubia and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional².

² A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.