European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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Please note that this product was withdrawn from the Community Register of designated Orphan Medicinal Products in November 2006 on request of the sponsor.

COMMITTEE FOR ORPHAN MEDICINAL PRODUCTS

PUBLIC SUMMARY OF POSITIVE OPINION FOR ORPHAN DESIGNATION OF boswellia serrata resin extract for the treatment of peritumoral oedema derived from brain tumours

On 21 October 2002, orphan designation (EU/3/02/117) was granted by the European Commission to Pharmasan GmbH, Germany, for boswellia serrata resin extract for the treatment of peritumoral oedema derived from brain tumours.

What is oedema derived from brain tumours?
A brain tumour is a disease in which cells begin to grow in the tissues of the brain. Tumour growth can produce an abnormal build-up of fluid between brain cells, with consequent swelling of the tissue around the tumour. This sign is called peritumoral oedema. The swelling causes an increase in the pressure inside the head. A high pressure may result in compression of different parts of the brain, causing damage to the brain tissues, and symptoms. Peritumoral oedema is life-threatening.

What are the methods of treatment available?
Steroid hormones (glucocorticoids) were authorised for the treatment of peritumoral oedema in the European Community at the time of the application for Orphan Designation. Glucocorticoids can be useful for long-term treatment, but can induce serious side effects. Boswellia serrata resin extract might be of potential significant benefit, as it might offer a better safety profile than glucocorticoids.

What is the estimated number of patients affected by the condition?
According to the information provided by the sponsor, peritumoral oedema derived from brain tumours was considered to affect about 55,000 patients in the European Union.

How is this medicinal product expected to act?
Boswellia serrata resin extract is a plant extract that can stop the production of certain substances called leukotrienes. Leukotrienes help regulate the state of blood vessels and airways, and influence the activities of white blood cells. Leukotrienes seem to contribute to the production of peritumoral oedema in the brain.

What is the stage of development of this medicinal product?
At the time of submission of the application for orphan designation, clinical trials in patients with peritumoral oedema derived from brain tumours were ongoing.

Boswellia serrata resin extract had not been marketed anywhere worldwide for peritumoral oedema derived from brain tumours or designated as orphan medicinal product elsewhere for this condition, at the time of submission.

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According to Regulation (EC) No 141/2000 of 16 December 1999, the Committee for Orphan Medicinal Products (COMP) adopted on 12 September 2002 a positive opinion recommending the grant of the above-mentioned designation.

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Opinions on orphan medicinal products designations are based on the following cumulative criteria: (i) the seriousness of the condition, (ii) the existence or not of alternative methods of diagnosis, prevention or treatment and (iii) either the rarity of the condition (considered to affect not more than five in ten thousand persons in the Community) or the insufficient return of development investments.

Designated orphan medicinal products are still investigational products, which have been considered for designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of the quality, safety and efficacy will be necessary before this product can be granted a marketing authorisation.

For more information:

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*Disclaimer: The number of patients affected by the condition is estimated and assessed for the purpose of the designation, for a European Community population of 377,000,000 (Eurostat 2001) and may differ from the true number of patients affected by the condition. This estimate is based on available information and calculations presented by the sponsor at the time of the application.