



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

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Committee for Orphan Medicinal Products

Public summary of negative opinion for orphan designation of 4-[[[4-(4-Chlorophenoxy)phenyl]sulfonyl]-methyl]tetrahydro- N-hydroxy-2H-pyran-4-carboxamide for prevention of graft rejection after liver transplantation

On 10 September 2008, the Committee for Orphan Medicinal Products (COMP) adopted a negative opinion on orphan designation of 4-[[[4-(4-Chlorophenoxy)phenyl]sulfonyl]-methyl]tetrahydro-N-hydroxy-2H-pyran-4-carboxamide for the prevention of graft rejection after liver transplantation. A negative decision was granted by the European Commission on 2 July 2009.

The sponsor applied for orphan designation on the basis of the seriousness and the rarity of the condition, as well as an assumption of potential benefit over currently available methods of treatment.

The negative opinion is based on the following reasons(s):

- although satisfactory methods of prevention of the condition have been authorised in the Community, sufficient justification has not been provided that 4-[[[4-(4-Chlorophenoxy)phenyl]sulfonyl]-methyl]tetrahydro-N-hydroxy-2H-pyran-4-carboxamide may be of significant benefit to the population at risk of developing the condition.

Requests for designation as an orphan medicinal product are made for investigational products. Absence of orphan designation does not preclude the development of this product, in particular through clinical trials. A marketing authorisation can still be obtained if quality, safety and efficacy are demonstrated.

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