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EMA recommends authorisation of Carbamazepin Tillomed (carbamazepine, 200 and 400 mg prolonged release tablets) in the EU

On 30 April 2020, the European Medicines Agency completed a review of Carbamazepin Tillomed and associated names following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Carbamazepin Tillomed outweigh its risks, and the marketing authorisation can be granted in Germany and the Member States of the EU where the company has applied for marketing authorisation (Croatia, Italy, Netherlands, Poland and Sweden), as well as in the United Kingdom.

What is Carbamazepin Tillomed?

Carbamazepin Tillomed is a medicine used to treat epilepsy, prevent psychosis (altered sense of reality) in patients with manic-depressive disorder, and treat facial pain caused by disrupted function of the trigeminal nerve in the face.

Carbamazepin Tillomed contains the active substance carbamazepine and is available as prolonged release tablets (200 and 400 mg) that release the active substance slowly.

Carbamazepin Tillomed was developed as a generic medicine. This means that Carbamazepin Tillomed was developed to contain the same active substance and work in the same way as a 'reference medicine' called Tegretol Prolonged Release 200 and 400 mg tablets.

Why was Carbamazepin Tillomed reviewed?

Laboratorios Tillomed Spain S.L.U. submitted Carbamazepin Tillomed to Germany for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States where the company has applied for a marketing authorisation (the 'concerned Member States', in this instance Croatia, Italy, Netherlands, Poland, and Sweden) and in the United Kingdom.

However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to EMA for arbitration on 6 March 2020.

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Because Carbamazepin Tillomed is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Tegretol Prolonged Release 200 and 400 mg tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

The grounds for the referral were concerns raised by the United Kingdom that stricter limits for differences in maximum blood levels should have been used for this type of medicine, since small variations in levels can lead to serious consequences. It was argued that if these stricter limits were used, the two medicines would not be considered bioequivalent.

What is the outcome of the review?

Based on evaluation of the currently available data, the Agency concluded that the stricter limits were not needed for prolonged release formulations of carbamazepine medicines, since the slower release reduces variation in the blood levels of the medicine. The Agency therefore concluded that Carbamazepin Tillomed is bioequivalent to its reference medicine and that its benefits outweigh its risks, and recommended that the marketing authorisation be granted in the concerned Member States.

More about the procedure

The review of Carbamazepin Tillomed was initiated on 6 March 2020 at the request of Germany under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on the marketing authorisation of Carbamazepin Tillomed on 25 June 2020.