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Questions and answers on Oxynal, Targin and associated names (oxycodone hydrochloride / naloxone hydrochloride)

Outcome of a procedure under Article 13(2) of Regulation (EC) 1234/2008

On 23 October 2014, the European Medicines Agency completed an arbitration procedure for Oxynal, Targin and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to arbitrate on a change to the marketing authorisation for these medicines to include a new use in the treatment of restless legs syndrome. The Committee concluded that the benefits of Oxynal, Targin and associated names outweigh their risks in the new use and the change to the marketing authorisation can be granted in Germany and the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

What are Oxynal and Targin?

Oxynal and Targin are medicines used to treat severe pain that can only be managed with opioids.

Oxynal and Targin contain two active substances: oxycodone hydrochloride, an opioid painkiller, and naloxone hydrochloride, an opioid antagonist, which is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors found locally in the gut.

Oxynal, Targin and associated names are marketed in all EU Member States except Croatia, Greece, Lithuania and Malta. The company that markets these medicines is Mundipharma GmbH.

Why was Oxynal and Targin reviewed?

Oxynal and Targin have been authorised in the EU under a mutual recognition procedure based on an initial authorisation granted by Germany. In November 2012, the company for Oxynal and Targin applied for an additional use in Germany: treatment of symptoms of severe to very severe restless legs syndrome when treatment with other medicines called dopaminergics has failed. Restless legs syndrome is a disorder where the patient has uncontrollable urges to move the limbs to stop uncomfortable, painful or odd sensations in the body, usually at night.

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The company wanted the authorisation for the additional use in restless legs syndrome to be recognised in the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom (the 'concerned Member States'). However, the Member States were unable to reach agreement on whether to accept this new indication and on 2 May 2014, Germany referred the matter to the CHMP for arbitration.

The grounds for the referral were concerns from the Netherlands that the data on Oxynal and Targin submitted in the application were not sufficient to demonstrate a positive benefit-risk balance in restless legs syndrome. In particular, there were concerns that the use of Oxynal and Targin could lead to tolerance and misuse and that this was not adequately studied in the clinical trial and the proposed measures to reduce the risk of tolerance and misuse were not considered sufficient.

What are the conclusions of the CHMP?

The Committee looked at the study presented by the company to support its application. Based on the evaluation of the available data and the scientific discussion within the Committee, the CHMP agreed that the study had convincingly shown that Oxynal and Targin are beneficial in the treatment of symptoms of severe to very severe restless legs syndrome when standard therapy has failed. Regarding the safety, the CHMP concluded that overall the risk of tolerance and misuse is considered low and that the proposed measures to reduce this risk are appropriate.

The CHMP therefore concluded that the benefits of Oxynal and Targin for restless legs syndrome outweigh their risks and recommended that the change to the marketing authorisation be granted in Germany and the concerned Member States.

The European Commission issued an EU-wide legally binding decision to implement this change on 22 December 2014.