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Questions and answers on Ethirfin and associated names (morphine sulphate, prolonged-release capsules, 20, 60, 120 and 200 mg)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure for Ethirfin and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to arbitrate on the renewal of the marketing authorisation for Ethirfin. The Committee concluded that the marketing authorisation should not be renewed, as patients taking Ethirfin and alcohol are at risk of developing serious side effects.

What is Ethirfin?

Ethirfin is a medicine that contains the active substance morphine sulphate. It is used to treat severe pain. Ethirfin is available as 'prolonged-release' capsules that release the active substance slowly. They are taken once a day.

Why was Ethirfin reviewed?

Ethirfin was authorised in the European Union (EU) under a mutual recognition procedure on the basis of the initial authorisation granted by Denmark on 15 July 2005. The company applied for the marketing authorisation to be renewed in Denmark (the 'reference Member State'). This renewal was to be recognised in Germany, Ireland, Italy and the United Kingdom (the 'concerned Member States'). Because these Member States were not able to reach an agreement, the German and United Kingdom medicines regulatory agencies referred the matter to the CHMP for arbitration on 30 October 2009.

The grounds for the referral were concerns that the active substance in the capsules could be released too quickly if the capsules are taken with alcohol, because they contain a 'polymethacrylate-triethylcitrate' coating to control the release of morphine and this coating is soluble in alcohol. The rapid release of the active substance is called 'dose dumping' and could put patients at risk of exposure to large doses of morphine, leading to side effects such as respiratory depression (an inhibition of breathing).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that there is a significant interaction between Ethirfin and alcohol, and that patients taking Ethirfin and alcohol are at risk of developing serious side effects. Therefore the benefits of Ethirfin do not outweigh its risks, and the marketing authorisation for Ethirfin should not be renewed in all concerned Member States.

The European Commission issued a decision on this opinion on 20 December 2010.