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Start of review of bromocriptine in preventing or supressing lactation

The European Medicines Agency has started a review of bromocriptine–containing medicines when taken by mouth for preventing or supressing lactation (milk production) in women following childbirth.

The review of bromocriptine was requested by the French medicines agency (ANSM) following concerns in France over rare but potentially serious or fatal side effects, particularly cardiovascular side effects (such as heart attack and stroke), neurological side effects (such as fits) and psychiatric side effects (such as hallucinations and manic episodes). ANSM considered that the risk of these events is not acceptable in view of the fact that lactation is a natural process that eventually stops if the infant is not breastfed, and that other authorised products are available if there is a need to suppress it.

The European Medicines Agency will now review the available data on the benefits and risks of bromocriptine medicines taken by mouth for preventing or supressing lactation, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

More about the medicine

Bromocriptine is used to prevent or suppress milk production in women who have given birth. Women may not always breastfeed after childbirth due to a variety of reasons ranging from stillbirth and HIV-infection of the mother to personal choice. Although milk production eventually stops, women in the meantime can experience breast engorgement, leakage of milk, discomfort and pain.

Bromocriptine is a dopamine receptor agonist. It activates the receptors for dopamine, a hormone that regulates the release of another hormone called prolactin, which controls lactation. As a result, bromocriptine prevents the secretion of prolactin, thereby preventing or suppressing milk production.

Bromocriptine is also used to treat other conditions, such as hyperprolactinaemia (high levels of prolactin in the body) and Parkinson's disease; however these uses are not included in this review.

Bromocriptine medicines have been authorised via national procedures in the following EU Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxemburg, Netherlands, Poland,

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Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom, as well as Norway. They are available on prescription as tablets and capsules, and have been marketed under various trade names (such as Parlodel) and as generics.

More about the procedure

The review of oral bromocriptine has been initiated at the request of France, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As bromocriptine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a medicines regulatory body representing the EU Member States.