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PRAC recommends restricted use of bromocriptine for stopping breast milk production

The medicine should not be used routinely for preventing or stopping milk production after childbirth

The European Medicines Agency has completed an EU-wide review of bromocriptine-containing medicines for preventing or suppressing lactation (breast milk production) in women after childbirth.

The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that the medicines only be used for this purpose (in strengths up to 2.5 mg) when there are compelling medical reasons for stopping lactation, such as to avoid further distress after loss of the baby during or just after childbirth, or in mothers with HIV infection, who should not breastfeed. Bromocriptine should not be used routinely for preventing or stopping milk production, nor to relieve symptoms of pain or swelling of the breasts after childbirth. Such symptoms can be managed by measures such as breast support or applying ice, and the use of painkillers if needed.

The Committee also concluded that bromocriptine must not be used in women at increased risk of serious side effects, including women with disorders that increase blood pressure or severe psychiatric disorders. Blood pressure should be monitored so that early signs of problems can be detected and treatment stopped immediately.

The review of bromocriptine was carried out at the request of the French medicines authority (ANSM) following concerns in France over increased reports of rare but potentially serious or fatal side effects, particularly cardiovascular side effects (such as heart attack and stroke), neurological side effects such as seizures (fits) and psychiatric side effects (such as hallucinations and manic episodes). ANSM considered that the risk of these events was not acceptable since lactation is a natural process that eventually stops if the infant is not breastfed, and other means of management are available.

The Committee therefore carefully assessed the available evidence of safety and effectiveness of bromocriptine-containing medicines for preventing or suppressing lactation before making its recommendations. The available evidence confirmed that bromocriptine was effective in preventing or suppressing lactation after childbirth but an association between bromocriptine treatment and events such as heart attack, stroke, fits, and psychiatric disorders could not be ruled out.

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The PRAC recommendation will now be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) which will adopt a final position[1].

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 for 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 mimics some of the actions of dopamine, a hormone that regulates the release of another hormone, prolactin, which in turn 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 for various indications 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, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom, as well as Norway. They are available on prescription for use by mouth in forms such 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 was initiated at the request of France on 17 July 2013, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. As bromocriptine-containing medicines are all authorised nationally, the PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position[1]. The CMDh is a regulatory body representing EU Member States, and is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

If the CMDh position is agreed by consensus, the agreement will be directly implemented by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission, for the adoption of an EU-wide legally binding decision.

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[1] The companies that market bromocriptine have the right to ask for a re-examination of the PRAC recommendation within 15 days of receipt of the PRAC recommendation, which would delay the expected time of finalisation of this review.