Start of review of bromocriptine in preventing or suppressing lactation

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Information on Bromocriptine

- Bromocriptine is used to 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 (increases the amount of a chemical in the brain). 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.
- In Malta, the following products containing bromocriptine are authorised for use;

Product Name	Active Ingredient	Formulation	License Number
Brameston Tablets 2.5mg	Bromocriptine mesilate 2.9mg	TABLET	AA084/07301
Parlodel 10mg Capsule	Bromocriptine 10mg (as mesilate)	CAPSULE, HARD	AA244/14602
Parlodel 2.5mg Tablets	Bromocriptine 2.5mg (as mesilate)	TABLET	AA806/01201

Information from European Medicines Agency about the safety concern

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 Pharmacovilance Risk Assessment Committee at 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 advice on the marketing authorisations of these medicines across the European Union (EU) which will be forwarded to the Member States (Co-ordination group for decentralised procedures) for adoption.

More information can be obtained from www.ema.europa.eu

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Bromocriptine containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Dr John J Borg PhD

Post-Licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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