

31st French Pharmacovigilance Meeting: selected presentations

The 31st French Pharmacovigilance Meeting took place in March 2010 in Bordeaux. Each year this conference examines adverse events reported to regional pharmacovigilance centres by healthcare professionals, as well as the French pharmacovigilance database.

The following articles will examine presentations having important practical implications, which provide useful feedback and encourage further reporting.

These presentations highlight the importance of reporting adverse effects, and their analysis by pharmacovigilance centres independent of the pharmaceutical industry, in providing transparent, high-quality information that serves patients' best interests.



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Inhibition of lactation: risks associated with dopamine agonists

● A survey conducted in Lyon, France, shows that many women are prescribed drugs, especially *bromocriptine*, to inhibit lactation. The authors highlight the high risk of severe and sometimes life-threatening adverse effects, especially cardiovascular and neurological disorders.

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In France, *bromocriptine* and *lisuride*, two rye ergot derivative dopamine agonists, are approved for inhibition of lactation. They carry a risk of arterial hypertension, stroke, hallucinations and seizures (1).

With support from the Rhône-Alps regional health insurance services, URCAM, the Lyon Regional Pharmacovigilance Centre (CRPV) conducted a survey of methods currently used to inhibit lactation in France (2). A questionnaire was sent to 618 maternity units in university, public and private hospitals. The authors analysed prescriptions reimbursed by the Rhône-Alps health insurance services for women aged 14 to 50 years who were discharged from a maternity unit between 1 January 2008 and 31 May 2009. They also analysed relevant reports recorded in the French national pharmacovigilance database (3).

Bromocriptine and dihydroergocryptine often used. The questionnaires (response rate 43%) revealed that a drug was used to inhibit lactation in 95% of cases; *bromocriptine* was prescribed in 89% of cases. *Dihydroergocryptine* and

cabergoline, two other rye ergot derivatives, were proposed as first-line or second-line choices in respectively 39% and 24% of cases.

Lisuride, homeopathy and non-drug measures were rarely recommended.

Analysis of prescription reimbursements showed an increase in *dihydroergocryptine* prescriptions and a decline in *bromocriptine* prescriptions. *Dihydroergocryptine* was prescribed more frequently to women receiving cardiovascular or psychotropic medications, suggesting that French prescribers prefer *dihydroergocryptine* over *bromocriptine* for women with cardiovascular or neuropsychiatric risk factors.

The authors also analysed reports of adverse effects implicating rye ergot derivatives used to inhibit lactation, recorded between November 1993 and December 2008 in the French national pharmacovigilance database, among women aged 14 to 50 years (a)(3).

Reports of sometimes serious cardiovascular reactions. There were 197 reports implicating *bromocriptine*; 77 of these cases were serious and included 2 deaths. The most frequent effects were cardiovascular disorders (74 cases), including 9 cases of myocardial infarction, 1 of which was fatal, and 29 cerebrovascular events, including 15 strokes (1 death) and 9 cases of benign cerebral angiopathy.

Neuropsychiatric reactions included seizures (4 cases), and onset or aggravation of psychiatric disorders (12 cases). Predisposing factors were present in

45 patients, including smoking (16 cases) and obesity (6 cases).

Eleven reports implicated *dihydroergocryptine*, including 1 case of benign cerebral angiopathy and 1 case of haemorrhagic stroke. Nine reports implicated *lisuride*. No adverse effects were attributed to *cabergoline*.

In practice. The absence of breastfeeding, without any other measures, is rarely associated with serious complications.

Paracetamol and non-drug measures are generally sufficient to relieve pain (experienced by 40% of women) and breast inflammation (10%).

Dopamine agonists derived from rye ergot have little place in the inhibition of lactation, especially when the frequency and potential severity of their adverse effects in this setting are taken into account (4).

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a- The indication "inhibition of lactation" was considered probable or certain in 78% of cases (ref 3).

Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Arrêter la montée de lait" Infos-Patients Prescrire. www.prescrire.org; 1 page.
2- Mirkou A et al. "Practices for inhibition of lactation in France" 31st Pharmacovigilance Meeting, Bordeaux: 23-25 March 2010. *Fundamental Clin Pharmacol* 2010; **24** (suppl. 1): 6 (abstract 26): full text 13 pages.

3- Mirkou A et al. "Pharmacovigilance of ergot derivatives used for lactation inhibition" 31st Pharmacovigilance Meeting, Bordeaux: 23-25 March 2010. *Fundamental Clin Pharmacol* 2010; **24** (suppl. 1): 73 (abstract 352). Full text 1 page.

4- Prescrire Editorial Staff "Inhibition of lactation after delivery" *Prescrire Int* 1995; **14** (20): 183-187.