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Agence nationale de sécurité du médicament et des produits de santé

Safety Information

This document was translated by the association "Timeo et les Autres". The original document can be accessed with the link below: http://ansm.sante.fr/content/download/46761/603478/version/2/file/pi-130225-Cytotec.pdf

Warning about the potential risks associated with off-label use of Cytotec (misoprostol) in the induction of labor and any other gynecological use

In France, the induction of labor after 37 weeks of amenorrhea can be considered for medical or non-medical purpose under certain conditions and in compliance with the rules of good practice when using products which have demonstrated to have a positive benefit-safety balance for this indication. The French National Security Agency (ANSM) warns healthcare professionals about the risks associated with off-label use of medicinal products that do not have a Marketing Authorization for the induction of labor.

In the case of the induction of labor after 37 weeks of amenorrhea, the use of unauthorized medicine products, whatever the route of administration, exposes the mother and the baby to serious risks. Indeed, severe adverse effects have been reported with the use of Cytotec when inducing the labor such as uterine rupture, hemorrhage or abnormal fetal heart rate.

in France, Cytotec (misoprostol) got its Marketing Authorisation (MA) in 1986. This medicine product is currently indicated for the treatment of active gastric or duodenal ulcers, gastro-duodenal lesions induced by nonsteroidal anti-inflammatory drugs (NSAIDs) or as a preventive treatment for gastric and duodenal lesions and severe complications induced by NSAIDs.

Off-label uses of Cytotec in obstetrics for induction of labor after 37 weeks of amenorrhea were reported to ANSM. So far, there are no safety data that proves a positive benefit-safety balance of Cytotec in this indication (induction of labor), regardless the route of administration. This off-label use can cause serious side effects for the mother and the baby.

The ANSM points out that, in France, the High Authority for Health (HAS) published in April 2008 professional recommendations that recall the conditions that allow an induction of labor, whether for medical reasons or not and methods that can be used for this induction. These methods include the sweeping of membranes and the use of specialities (containing dinoprostone) approved for this indication. To date, misoprostol has no Marketing Authorization for the induction of labor.

Note that in October 2005, after fatal issues were reported in the United States concerning an off-label use of vaginal misoprostol in abortion, the ANSM had sent to prescriptors an information to recall the conditions and rules of a proper use of mifepristone / misoprostol in abortion.

The ANSM recalls that any adverse effect must be reported to the Regional Centre for Pharmacovigilance (CRPV) whose details can be found on the website of the ANSM: www.ansm.sante.fr. Patients can now report adverse effects themselves as well as approved associations of patients.

Nota Bene: This warning also applies to Gymiso ® that should not be used in the induction of labor.

Useful links:

- IVG médicamenteuse : rappel des conditions d'utilisation de la mifépristone et du misoprostol : Lettre aux professionnels de santé (18/10/2005) : http://ansm.sante.fr/S-informer/Presse-Communiques-Points-presse/IVG-medicamenteuse-rappel-des-conditions-d-utilisation-de-la-mifepristone-et-du-misoprostol/(language)/fre-FR

[1] Déclenchement artificiel du travail à partir de 37 semaines d'aménorrhée. Recommandations professionnelles de la HAS. Avril 2008. http://www.has-sante.fr/portail/upload/docs/application/pdf/declenchement_artificiel_du_travail_-_recommandations.pdf