



## Novartis Warns Doctors on Off-Label Femara Use

ZURICH (Reuters) Nov 30 - Novartis has warned doctors not to use its hormone-based breast cancer drug Femara (letrozole) to help women become pregnant after reports of adverse events following such off-label use.

Novartis had found 13 reports of cases where individual doctors had prescribed Femara for ovulation induction in its safety database, a spokeswoman said.

This led to birth defects in two cases and two spontaneous miscarriages in two others. There were four normal births, while there was a lack of information in the five remaining cases.

"Novartis simply encouraged physicians and patients to stick to the prescribed information," the spokeswoman said.

"This indication is not approved and Novartis never did anything to promote it."

Femara is for use in postmenopausal women only, she said, but some doctors across the world have prescribed the drug to treat infertility in women, leading to the reports.

However, Novartis is seeking wider indications for Femara. U.S. regulators in August agreed to speed up their review process on whether it should be used by women with breast cancer immediately following surgery to remove a tumour.

Femara is the second in a new class of hormone-based breast-cancer treatments called aromatase inhibitors to have demonstrated an advantage over tamoxifen, currently standard treatment for women with breast cancer.

### Source:

<http://www.medscape.com/viewarticle/518136>

### Response by ASJOG

ASJOG previously published an article on drugs used in induction of ovulation and included letrozole among those drugs.

We now feel it is our duty to publish this announcement. We regard this event as a solid proof of our main Raison D'être (reason of existence), since it shows how rapidly and dramatically medical knowledge changes.

The Editorial Board

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