

PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
HERCEPTIN® (trastuzumab)



April 21, 2009

Subject: Association of HERCEPTIN® (trastuzumab) with Oligohydramnios (too little amniotic fluid)

Hoffmann-La Roche Limited, in consultation with Health Canada, would like to inform patients of important new safety information regarding the use of HERCEPTIN® (trastuzumab) during pregnancy.

HERCEPTIN (trastuzumab) is used to treat certain patients with early stage breast cancer or certain patients with breast cancer that has spread.

Please note the following new safety information for the use of HERCEPTIN:

Cases of oligohydramnios (low levels of amniotic fluid) during the second and third trimesters have been reported in pregnant women receiving HERCEPTIN.

- \$ Several cases of oligohydramnios were reported between 2004 and August 2008 in patients receiving Herceptin.
- \$ In some of the reports, a decrease in amniotic fluid level was diagnosed seven weeks after starting HERCEPTIN.
- \$ If HERCEPTIN is used during pregnancy, your physician should monitor the amount of amniotic fluid
- \$ Careful fetal monitoring of your baby is recommended after diagnosing oligohydramnios, as is usually done in such situations.
- \$ HERCEPTIN should not be used during pregnancy unless the potential benefit for the mother outweighs the potential risk to the baby.

Oligohydramnios is the condition of having too little amniotic fluid. Amniotic fluid is the liquid that surrounds your baby as he/she grows inside your womb during pregnancy. The fluid, or “waters”, protects the baby from being hurt if you have a blow to your abdomen or your abdomen is compressed. The fluid also plays an important part in protecting the baby against infection and in helping his/her lungs and digestive system to mature. The consequences of oligohydramnios for the baby depend on what is causing the problem, how far along you are, and the amount of fluid you have. Your doctor will be able to provide you with further information, depending on your specific case.

It is important to carefully read the Consumer Information (package insert) section of the Product Monograph as this gives details about what information you should tell your doctor.

Specifically BEFORE you use HERCEPTIN, talk to your doctor or pharmacist if you plan to become pregnant. Please notify your doctor even if you are only breast-feeding a child.

If you become pregnant while taking HERCEPTIN notify your doctor immediately.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions underestimate the risks associated with medicines. Any case of serious oligohydramnios or other serious or unexpected adverse reactions in patients receiving HERCEPTIN should be reported to Hoffmann-La Roche or Health Canada at the following addresses:

Hoffmann-La Roche Limited
Drug Safety Department
2455 Meadowpine Boulevard
Mississauga, Ontario, L5N 6L7
or call toll free at: 1-888-762-4388
or Fax at: 905-542-5864
or email to: mississauga.drug_safety@roche.com

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866-234-2345
Fax: 866-678-6789
CanadaVigilance@hc-sc.gc.ca

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738:

Should you have any questions or require additional information regarding the use of HERCEPTIN, please contact the Drug Information Department at Hoffmann-La Roche Limited at 1-888-762-4388 from 8:30 a.m. to 4:30 p.m. Monday to Friday Eastern Standard Time.

Sincerely,

Original signed by

Lorenzo Biondi,
Vice President, Medical and Regulatory Affairs
Hoffmann-La Roche Limited