PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on KETEK (telithromycin)

sanofi aventis
Because health matters

2006/10/03

Dear Sir/Madam,

Subject: **Updated safety information on the antibiotic KETEK (telithromycin) and liver problems, worsening of myasthenia gravis and fainting**

Sanofi-aventis Canada Inc., in consultation with Health Canada, wishes to provide Canadian consumers with important updated safety information regarding KETEK (telithromycin) tablets. The following information was obtained from reports of side effects received from health care professionals and consumers. Some patients have experienced liver problems during or following treatment with KETEK. Rare cases of severe liver injury have been reported and have, in isolated cases, resulted in death. In myasthenia gravis patients, reports have also included life-threatening breathing trouble and death. Fainting (also called syncope) has also been reported in some patients taking Ketek.

- **Liver Problems:** There have been rare reports of severe liver injury, which can be life-threatening, in patients using KETEK. (The signs and symptoms of liver failure include fatigue, malaise, loss of appetite, nausea, yellow skin and dark-colored urine.)
- **Worsening of Myasthenia Gravis:** In patients with a neuromuscular disease known as myasthenia gravis, there have been reports of a sudden worsening of symptoms during treatment with KETEK.
- **Fainting:** KETEK can cause fainting in some patients, especially those who are experiencing severe nausea, vomiting or light-headedness.

KETEK (the brand name for telithromycin) has been available in Canada since 2003 and is used for the treatment of some types of pneumonia, exacerbation of chronic bronchitis, throat infections and sinus infections.

Patients who have been prescribed KETEK and are not suffering side effects should continue taking their medicine, unless otherwise directed by their health care provider. Side effects to watch out for and what to do about them are described below.

Liver Problems

Before using KETEK, tell your doctor if you have liver disease, or if you have ever had jaundice (yellowing of the skin and eyes, dark urine) while taking KETEK. You should not take KETEK if you have ever experienced significant liver injury and/or yellowing of the skin or eyes while taking KETEK in the past.

KETEK should not be used if you have ever had an allergic reaction to KETEK (telithromycin) tablets or to any macrolide-type of antibiotic, such as erythromycin, azithromycin (Zithromax), or clarithromycin (Biaxin).

If you experience any signs or symptoms of liver disease, such as: loss of appetite, nausea, fatigue, jaundice (yellow colour to the skin and/or eyes), dark urine, light-coloured stools, generalised itching or abdominal pain, you should not take your next dose of KETEK, and either call your doctor immediately, or go to a clinic.

Worsening of Myasthenia Gravis

Before using KETEK, tell your doctor if you have a neuromuscular disease known as myasthenia gravis. Sudden worsening of the symptoms of myasthenia gravis has been reported in patients with myasthenia gravis during the treatment with KETEK. **KETEK is not recommended in patients with myasthenia gravis unless no other therapeutic alternatives are available.**

If you have myasthenia gravis and experience any worsening of your symptoms during treatment with KETEK, you must stop your treatment with KETEK and seek immediate medical attention.

Fainting

Before using KETEK, tell your doctor if you have fainted after taking any medication.

KETEK may cause fainting, especially if you are already experiencing severe nausea, vomiting, and/or light-headedness. If these symptoms occur, avoid driving, operating machinery, or engaging in hazardous activities. If you faint during treatment with KETEK, you should not take your next dose of KETEK, and either call your doctor or go to a clinic.

Sanofi-aventis Canada Inc. has sent a letter to health professionals informing them of this new safety information. A copy of the Healthcare professional letter and this communication are available on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html).

Complete product information is available in the official Canadian Product Monograph (see Part III: CONSUMER INFORMATION).

Reporting of Adverse Reactions

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 are generally presumed to underestimate the risks associated with health product treatments. Any case of liver problems,

worsening of myasthenia gravis, fainting or any other suspected Adverse Drug Reactions in patients receiving KETEK should be reported to sanofi-aventis Canada Inc. or Health Canada at the following addresses:

Any suspected adverse reaction can be reported to:
sanofi-aventis Canada Inc.:
Toll-free telephone: 1-800-265-7927
Internet: www.sanofi-aventis.ca

Regular mail:
sanofi-aventis Canada Inc.
2150 St. Elzear Blvd. West
Laval, Quebec
H7L 4A8

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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
cadrmp@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

Sincerely,

original signed by

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