European Medicines Agency
Press office

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Questions and Answers on the EMEA's action regarding the safety of Ketek (telithromycin)

What is Ketek?
Ketek, which contains telithromycin, is an antibiotic indicated to treat respiratory tract infections such as infections of the throat, infections of the sinuses, chest infections in patients with long-standing breathing difficulties and pneumonia.
Ketek has been authorised by the European Commission and is marketed within the European Union in Belgium, Cyprus, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Portugal, Slovenia, Spain, Sweden and the United Kingdom.

What is the issue with Ketek's safety?
Ketek can cause yellowing of the skin and eyes, dark urine, itching, loss of appetite or abdominal pain, which are signs and symptoms of liver disease (hepatitis). This has been known since the product was first authorised, in June 2001, and is reflected in the Product Information.

What action is the EMEA taking?
The European Medicines Agency (EMEA) has reviewed the reports it has received on patients who have had severe liver disorders when taking Ketek. As a result, the EMEA has now asked the company who markets Ketek (Aventis Pharma S.A.) to reinforce its warning in the information it provides to patients and to doctors that the product can cause liver disorders. This is a precaution until more is known about the issue.

Why did the EMEA review the information?
The EMEA, as part of its continuous monitoring of the safety of medicines, has received and assessed reports of cases of serious liver disorders with Ketek (including hepatitis and liver failure). The EMEA is currently assessing more cases of serious liver disorders (including cases of liver failure) in patients receiving Ketek.

Three of the serious cases already known to the EMEA were described in the online edition of a medical journal, "Annals of Internal Medicine", on 20 January 2006.

What are the consequences of the EMEA's action for patients and doctors?
Doctors already know about the risk of liver problems with Ketek. They are being made aware that the problems can be serious and even fatal, and that the problems may start during or immediately after treatment. In most cases, the problems disappear when treatment with Ketek is stopped. Doctors must also be careful when prescribing Ketek to patients who have liver impairment (when the liver does not function as well as normal).
Patients who are taking Ketek and develop signs and symptoms of a liver disease, such as lack of appetite, yellowing of the skin, dark urine, itching or tender abdomen (tummy), should stop treatment and contact their doctors.

Are there any further steps?
The Agency has started a full review of the risk/benefit of Ketek, as part of the renewal of the authorisation (the renewal procedure should be finalised in June 2006)[1].

[1] All medicines authorised by the European Commission are granted marketing authorisations that are valid for 5 years. The marketing authorisation holder can ask for the renewal for this authorisation.

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