EMA/719155/2012
EMEA/H/C/000354

EPAR summary for the public

Ketek

telithromycin

This is a summary of the European public assessment report (EPAR) for Ketek. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ketek.

What is Ketek?

Ketek is a medicine that contains the active substance telithromycin. It is available as tablets (400 mg).

What is Ketek used for?

Ketek is used to treat adults with mild or moderate community-acquired pneumonia (an infection of the lungs that is caught outside of hospital).

It is also used to treat adults with the following infections when they are caused by bacteria that are or could be resistant (insensitive) to beta-lactams or macrolides (types of antibiotic):

- acute exacerbation (flare-up) of chronic bronchitis (long-lasting inflammation of the airways in the lungs);
- acute sinusitis (short-lived infection of the sinuses, air-filled passageways in the bones around the nose and eyes).

Ketek is also used to treat patients aged 12 years or over who have tonsillitis or pharyngitis (infections of the tonsils or throat) caused by the bacterium *Streptococcus pyogenes*. It is used when beta-lactams are not appropriate, in countries or regions where there are high levels of resistance to macrolides.

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Prescribers should consider official guidance on the use of antibacterial agents and local levels of resistance to antibiotics.

The medicine can only be obtained with a prescription.

How is Ketek used?

The recommended dose of Ketek is 800 mg (two tablets) once a day. The tablets should be swallowed whole with water. Taking Ketek at bedtime may reduce the potential impact of side effects such as visual disturbances and loss of consciousness. For pneumonia, the tablets should be taken for seven to 10 days. For the other infections, they are taken for five days.

A lower dose may be needed in patients who have severe kidney problems. For more information, see the package leaflet.

How does Ketek work?

The active substance in Ketek, telithromycin, is an antibiotic belonging to the class 'ketolides'. These are closely related to the macrolides. Telithromycin works by blocking the bacteria's ribosomes (the parts of the cells where proteins are produced), inhibiting the growth of the bacteria. The full list of bacteria against which Ketek is active can be found in the summary of product characteristics (also part of the EPAR).

How has Ketek been studied?

Ketek has been studied in 10 main studies involving a total of over 4,000 patients. Four studies looked at its effects in mild to moderate community-acquired pneumonia, two looked at acute sinusitis, two looked at acute exacerbations of chronic bronchitis and two looked at tonsillitis or pharyngitis. All but two of the studies compared Ketek with other antibiotics. The main measure of effectiveness was the proportion of patients who were cured at the end of treatment as determined by a reduction in symptoms, or who had 'satisfactory' reductions in the amount of bacteria detected in samples taken from the throat.

What benefit has Ketek shown during the studies?

Ketek was as effective as the comparator antibiotics. For pneumonia and chronic bronchitis, Ketek was as effective as amoxicillin, clarithromycin, trovafloxacin, amoxicillin/clavulanic acid and cefuroxime axetil, with between 82 and 95% of the patients having no symptoms at the end of treatment. In patients with acute sinusitis, five- and 10-day courses of Ketek led to similar cure rates, which were similar to that seen with amoxicillin/clavulanic acid. For tonsillitis or pharyngitis, between 84 and 92% of the patients taking Ketek, penicillin or clarithromycin had a satisfactory reduction in bacterial levels in samples taken from the throat.

What is the risk associated with Ketek?

The most common side effect with Ketek (seen in more than 1 patient in 10) is diarrhoea. For the full list of all side effects reported with Ketek, see the package leaflet.

Ketek must not be used in people who are hypersensitive (allergic) to telithromycin, any macrolides, or any of the other ingredients. It must not be used in patients with myasthenia gravis (a disease of the nerves causing muscle weakness), or who have had hepatitis (inflammation of the liver) or jaundice when they have taken telithromycin in the past. Ketek must not be taken by patients with a history or

a family history of 'long QT syndrome' or with 'acquired QT interval prolongation' (disruption of the heartbeat). It must also not be used with a number of medicines. For the full list of restrictions, see the package leaflet.

Why has Ketek been approved?

The CHMP concluded that Ketek's benefits are greater than its risks and recommended that it be given marketing authorisation. However, the Committee noted that Ketek is associated with a greater risk of certain side effects than other antibiotics. Some of these side effects can be serious, including a worsening of myasthenia gravis, transient loss of consciousness and temporary disturbances to vision. Therefore, the Committee decided that its use should be reserved to the treatment of community-acquired pneumonia, to the treatment of bronchitis and sinusitis when caused by bacteria that are resistant to beta-lactam or macrolide antibiotics, and to tonsillitis/pharyngitis when these antibiotics cannot be used.

Other information about Ketek

The European Commission granted a marketing authorisation valid throughout the European Union for Ketek on 9 July 2001.

The full EPAR for Ketek can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Ketek, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.