



PRESS RELEASE

EMEA recommends restricted use of oral norfloxacin-containing medicines in urinary infections

The European Medicines Agency has recommended restricting the use of oral norfloxacin-containing medicines in urinary infections. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the marketing authorisations for oral norfloxacin-containing medicines, when used in the treatment of acute or chronic complicated pyelonephritis (kidney infection), should be withdrawn because the benefits of these medicines do not outweigh their risks in this indication. This is based on the fact that the efficacy has not been adequately demonstrated for this type of infection.

Norfloxacin is a fluoroquinolone antibiotic. Medicines containing norfloxacin are authorised in all European Union (EU) Member States under various trade names for the treatment of infections, including simple or complicated urinary tract infections, infection of the prostate, uncomplicated gonorrhoea, several types of gastroenteritis and conjunctivitis.

The CHMP review of norfloxacin medicines was initiated on the request of the Belgian medicines regulatory agency. They questioned the efficacy of oral formulations of the medicine for complicated pyelonephritis, in comparison with other fluoroquinolones. In current practice, this disease is usually treated using either injectable antibiotics, or other fluoroquinolones taken by mouth or given by injection.

Following evaluation of information provided by the companies, the CHMP, at its July 2008 meeting, noted that there was not enough clinical data to demonstrate the efficacy of oral treatment with norfloxacin-containing medicines in complicated pyelonephritis. Therefore, the CHMP concluded that the use of oral norfloxacin-containing medicines in the treatment of acute or chronic complicated pyelonephritis could no longer be supported.

The recommendation of the CHMP does not have an impact on the use of oral norfloxacin-containing medicines in other types of infection.

Doctors should not prescribe oral norfloxacin for complicated pyelonephritis and should consider switching patients already taking oral norfloxacin for this type of infection to an alternative antibiotic. Patients who are taking oral formulations of norfloxacin-containing medicines to treat complicated pyelonephritis should discuss their treatment with their doctor if they continue to have symptoms or at their next scheduled visit.

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NOTES

1. More information is available in a [question-and-answer document](#).
2. Medicines containing norfloxacin include: Alenbit; Amicrobin; Baccidal; Bactracid; Barazan; Besflox; Constilax; Diperflox; Docnorflox; Esclebin; Firin; Flossac; Floxacin; Floxolone; Fluseminal; Grenis; Gyrablock; Lexinor; Lorcamin; Nalion; Nolicin; Norbactin; Norflocux; Norflohexal; Norflok; Norflosal; Norflox; Norfloxax; Norfloxacin; Norfloxacina; Norfloxacine; Norfloxacino; Norfluxx; Norocin; Noroxin; Noroxine; Norquin; Norsept; Pistofil; Renoxacin; Sebercim; Senro; Setanol; Sinobid; Sofasin; Steinaclox; Trizolin; Urobacid; Uroctal; Uroflox; Urospes; Uticina; Utinor; Vetamol; Xasmun; Zoroxin.

3. The review procedure was initiated by Belgium under Article 31 of Directive 2001/83/EC, as amended. These types of referral may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information. The CHMP was asked to give an opinion on whether the benefits of norfloxacin medicines in this indication outweigh its risks and whether the indication should be maintained, varied, suspended or withdrawn from the marketing authorisations for oral formulations of products containing norfloxacin across the European Union.
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at <http://www.emea.europa.eu>.

Media enquiries only to:

Martin Harvey Allchurch or Monika Benstetter

Tel. (44-20) 74 18 84 27

E-mail: press@emea.europa.eu