



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA starts review of Rifadin oral suspension and syrup, a liquid formulation of the antibiotic rifampicin

Review will assess impact of ingredient diethanolamine on the benefit-risk balance

EMA's committee for human medicines (CHMP) has started a review of Rifadin 20 mg/ml oral suspension and syrup, a medicine containing the antibiotic rifampicin which is used to treat tuberculosis and other serious infections.

Rifadin is one of several rifampicin-containing medicines authorised for use in the EU. However, EMA's review is limited to a specific formulation of Rifadin, the 20 mg/ml oral suspension and syrup. The review follows concerns regarding the levels of one of the medicines' ingredients (excipients), diethanolamine (DEA).

DEA is used to ensure that the active substance is evenly distributed in the liquid and to maintain the acidity that is required for the medicine's stability and tolerability. However, DEA has been classified as a possible carcinogen based on studies involving rodents who were exposed over a long period of time to very high doses. This means that long-term exposure above certain levels may increase the risk of some cancers. However, the doses used in these studies were much higher than the amounts people would normally be exposed to when taking medicines that contain DEA.

In 2019, the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)¹ requested that marketing authorisation holders assess the risks associated with DEA and either reformulate affected medicines so they don't contain this ingredient or justify why DEA could not be replaced with an alternative².

The current review was started because, to date, the company that markets Rifadin 20 mg/ml oral suspension and syrup has not submitted a proposal for a new formulation of the medicine that does not contain the ingredient DEA.

¹ The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.

² Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). *Minutes of the CMDh meeting held on 23–25 April 2019*. Amsterdam: Heads of Medicines Agencies; 2019. Available at: https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Agendas_and_Minutes/Minutes/2019_04_CMDh_Minutes.pdf



The CHMP will now assess the impact of this issue on the benefits and risks of Rifadin 20 mg/ml oral suspension and syrup and will issue a recommendation on whether the marketing authorisation in the EU should be maintained, amended, suspended or revoked.

Patients, parents or caregivers who have any questions about current treatment should speak to the patients' doctor or pharmacist. Treatment should not be stopped or changed without first speaking to the patients' doctor, as this may negatively affect the management of their condition.

More about the medicine

Rifadin is the trade name of an oral suspension and syrup containing the antibiotic rifampicin (20 mg/ml). It is authorised in Austria, France, Ireland, Italy, Netherlands, Northern Ireland, Portugal and Spain. In Austria, France and Spain the medicine is marketed under the trade names, Rifoldin, Rifadine and Rifaldin, respectively. Rifadin 20 mg/ml oral suspension and syrup is used mainly in children.

Rifadin is also available in other pharmaceutical forms including capsules and powder and solvent for concentrate for solution for infusion.

In addition, several other medicines containing rifampicin are authorised in the EEA under different trade names. These are available in other pharmaceutical forms and strengths, such as capsules, granules for suspension and powder for solution for infusion, as well as in combination with isoniazid (Rifinah film-coated tablets). However, EMA's review is limited to one formulation of Rifadin, the 20mg /ml oral suspension and syrup.

Rifampicin is used to treat tuberculosis (TB), a serious and life-threatening bacterial infection that mainly affects the lungs but can also involve other parts of the body. Rifampicin is sometimes also used to treat other serious infections.

Treatment with rifampicin often lasts for several months. For most patients with TB that respond to standard treatment, treatment typically lasts at least six months, although a longer duration may be required depending on the type and severity of the infection and the patient's response to treatment.

More about the procedure

The review of Rifadin 20 mg/mL oral suspension and syrup was initiated at the request of the Dutch medicines agency (MEB), under [Article 31 of Directive 2001/83/EC](#).

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.