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

02/07/2026 | Circular Number P07/2026

Information on Rifadin oral suspension

- Rifadin is the trade name of an oral suspension and syrup containing the antibiotic rifampicin (20mg/ml). Rifadin is also available in other pharmaceutical forms including capsules and powder and solvent for concentrate for solution for infusion.
- 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.

In Malta the following products are authorised through 126a licensing procedure:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
RIFAMPICIN 20mg/ml	Rifadin Oral suspension 20 mg/ml	Oral Suspension	POM	AA565/04105	Central Procurement & Supplies Unit
RIFAMPICIN 100mg/5ml	Rifadin 100mg/5ml Oral Suspension	Oral Suspension	POM	AA565/04104	Central Procurement & Supplies Unit

Information from the EMA about the safety concern

- The review of Rifadin 20 mg/mL oral suspension and syrup was initiated at the request of the Dutch medicines agency (MEB)
- 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.
- EMA's committee for human medicines (CHMP) has started a review of Rifadin 20mg/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 20mg/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.
- 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) requested that marketing authorisation holders assess the risks associated with DEA and either reformulate affected medicines so they do not contain this ingredient or justify why DEA could not be replaced with an alternative.
- 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.

For more information visit https://www.ema.europa.eu/en/medicines/human/referrals/rifadin-oral-suspension-syrup-associated-names on the European Medicines Agency's website and the SmPC for Rifadin 20 mg/mL.

In Malta

For Patients

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.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Rifadin 20 mg/mL. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Archived Safety Circulars
Archived Direct Healthcare Professional Communications
Archived Risk Minimisation Measures

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

Malta Medicines Authority

Sir Temi Żammit Buildings

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