23 May 2025
EMA/165709/2025

Changes to the use of antibiotic azithromycin

Recommendations aim to optimise use and minimise development of antimicrobial resistance

EMA's human medicines committee (CHMP) has recommended several changes to the way the antibiotic azithromycin is used in the EU, including the removal of certain indications. These recommendations aim to optimise the use of this common antibiotic and minimise the development of antimicrobial resistance – the ability of microorganisms to become resistant to antimicrobials.

Azithromycin has been used for decades to treat a wide range of infectious diseases, both in children and adults. It is included in the World Health Organization (WHO) list of essential medicines, which highlights its importance for public health.

However, azithromycin is also classified by WHO as an antibiotic that carries a higher risk of antimicrobial resistance and is included in WHO's Watch category (AWaRe classification). Data show that antimicrobial resistance against this antibiotic has increased in recent years.

Medicines in WHO's Watch category should be prioritised as key targets for prudent use and monitoring. However, consumption data indicate an increased use of azithromycin medicines in recent years. A recent EMA-commissioned study, performed by DARWIN EU, showed a broad use of this antibiotic across the EU, both in adults and children.

To promote a more rational use of this antibiotic based on current evidence and preserve its effectiveness, the CHMP re-evaluated the benefits and risks of azithromycin medicines given by mouth or infusion (drip) into a vein for the various authorised uses.

The committee reviewed all available data, including results from clinical studies, information about resistance of pathogens relevant for the approved indications in the EU, a risk assessment on the probability of resistance development during treatment as well as recommendations in current national and European treatment guidelines.

Uses to be refined and harmonised

Based on this comprehensive review, the CHMP recommended amending most of the authorised uses of azithromycin medicines given by mouth or infusion. The changes are intended to align the authorised uses with the latest data and to make them more precise. They also aim to harmonise the dosing recommendations and contraindications across all products as well as the information about interactions with other medicines, use in pregnancy, side effects and relevant data from clinical studies.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The revisions mainly concern:

- Upper and lower respiratory tract infections (infections of the nose, throat, airways and lungs), such as acute bacterial sinusitis, acute streptococcal tonsillitis and pharyngitis, acute exacerbations of chronic bronchitis and community-acquired pneumonia;
- Sexually transmitted diseases, such as urethritis and cervicitis caused by *Chlamydia trachomatis*, or *Neisseria gonorrhoeae*;
- Infections of the female reproductive system, such as pelvic inflammatory disease;
- Dental infections, such as periodontal abscesses and periodontitis;
- Treatment and prevention of types of *Mycobacterium avium* complex infections in people living with HIV-1 infection.

The full list of revised uses can be found in the published product information.

Uses to be discontinued

In addition, the Committee recommended discontinuing the use of azithromycin taken by mouth (currently authorised in few Member States) for:

- moderate acne vulgaris (also known as acne), a condition in which pores in the skin become blocked with excess oil and skin cells;
- eradication of *Helicobacter pylori*, a bacterium that causes infection in the stomach which can lead to chronic inflammation and ulcer;
- prevention of exacerbations (attack) of eosinophilic and non-eosinophilic asthma, two different types of asthma.

The Committee considered that the evidence available is not sufficient to support the effectiveness of azithromycin in these indications and therefore concluded that the benefits do not outweigh the risks.

New warning

The CHMP also recommended including a warning in the medicines' product information to highlight the risk of antimicrobial resistance. This will explain that azithromycin could favour the development of resistance due to the long-lasting, decreasing levels in plasma and tissues after the end of treatment.

The warning will state that azithromycin should only be initiated after a careful assessment of the benefits and the risks, considering the local prevalence of resistance, and when preferred treatment regimens are not indicated.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

Information for patients

- The antibiotic azithromycin has been used for decades to treat a wide range of infections, both in children and adults.

- However, the resistance of pathogens against this antibiotic has increased in recent years. As it is crucial to maintain the effectiveness of this antibiotic, which is active against many types of bacteria, EMA has reviewed all available data to promote a more rational use of this antibiotic based on current evidence.
- As a result of this review, most of the authorised uses have been amended to make them more precise. The dosing recommendations, including per age groups, have also been harmonised.
- In addition, azithromycin can no longer be used in the following cases where its effectiveness has not been clearly demonstrated: moderate acne vulgaris (also known as acne); eradication of *Helicobacter pylori* (a bacterium that causes infection in the stomach which can lead to chronic inflammation and ulcer); and prevention of exacerbations (attack) of eosinophilic and non-eosinophilic asthma, two types of asthma.
- If you have been prescribed an azithromycin medicine and have questions about your treatment, speak to your doctor or pharmacist.

Information for healthcare professionals

- To promote a more rational use of oral and intravenous azithromycin medicines and preserve their effectiveness, the CHMP has re-evaluated their benefits and risks in the various authorised uses.
- Based on this comprehensive review, the Committee refined the authorised uses to make them more precise and aligned with available data and current medical terminology. The dosing recommendations have also been harmonised. Complete information on the authorised uses can be found in the amended product information.
- In addition, the CHMP found a negative benefit-risk balance for oral formulations of azithromycin in the following indications: moderate acne vulgaris; eradication of *Helicobacter pylori* and prevention of exacerbations of eosinophilic and non-eosinophilic asthma. These indications will then be removed from the product information.
- A new warning will be included in the summary of product characteristics regarding the development of antimicrobial resistance and the need to assess the benefits and the risks, considering the local prevalence of resistance, and when preferred treatment regimens are not indicated.
- This review was carried out as available consumption data suggest that azithromycin has been used increasingly in recent years, which conflicts with recommendations about prudent use of medicines included in WHO's Watch category.
- A study commissioned by EMA and performed by DARWIN EU (DARWIN study report C1-003), which analysed the prescription of the 141 antibiotics in WHO's Watch category between 2012 and 2021 in 5 European countries (France, Germany, Spain, the Netherlands, and United Kingdom), found that azithromycin was among the top 5 most prescribed antibiotics in most databases assessed, and within the top 10 in all the databases included.
- At the same time, data from the ATLAS and SENTRY databases have shown an increasing global prevalence of azithromycin resistance among bacterial strains, with resistance developing among pathogens linked to the approved indications of azithromycin in the EU/European Economic Area.

More about the medicine

Azithromycin is one of a group of antibiotics known as macrolides. It can be given by mouth (tablets and oral solution for children) or infusion (drip) into a vein to treat infections caused by Gram-positive and Gram-negative bacteria, such as, but not limited to, upper and lower respiratory tract infections, such as community-acquired pneumonia.

Azithromycin systemic medicines have been authorised nationally in the EU for many years and are marketed under a variety of brand names.

Some azithromycin medicines are also approved in the EU for topical use (as eye drops). These medicines are out of scope for this review procedure.

More about the procedure

The review was initiated on 30 October 2023 at the request of the German Federal Institute for Drugs and Medical Devices, under Article 31 of Directive 2001/83/EC.

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