



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Bacterial lysate medicines for respiratory conditions to be used only for prevention of recurrent infections

EMA is recommending that bacterial lysate medicines authorised for respiratory conditions should only be used for the prevention of recurrent respiratory infections, with the exception of pneumonia. This follows a review that concluded that there are no robust data showing that these medicines are effective at treating existing respiratory infections, or for the prevention of pneumonia, therefore they should not be used for these purposes.

In the review, EMA's human medicines committee (CHMP) considered the results of clinical studies, data on side effects reported with these medicines, and advice from an expert group on infectious diseases.

Although data are limited, the review found some evidence of effectiveness of these medicines in the prevention of recurrent respiratory tract infections and the safety profile is in line with what is expected for this type of product. The CHMP therefore recommended that use of the medicines for prevention can continue, but the companies must provide further data on safety and effectiveness from new clinical studies by 2026.

Information for patients

- Bacterial lysate medicines should not be used to treat existing infections of the airways or to prevent pneumonia (a lung infection) because there are not enough data to show that they work for these uses.
- Bacterial lysate medicines can continue to be used to prevent infections of the airways (except pneumonia) from coming back in patients who regularly get infections.
- If you have an infection and are taking a bacterial lysate medicine to treat it, or if you are taking one of these medicines to prevent pneumonia, contact your doctor or pharmacist for advice on alternatives.
- If you have any questions or concerns about your medicine, discuss them with your doctor or pharmacist.

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Information for healthcare professionals

- The indications of bacterial lysate medicines are being restricted to prophylaxis of recurrent respiratory tract infections, with the exception of pneumonia. Bacterial lysate medicines should not be prescribed for treatment of existing respiratory infections or for prophylaxis of pneumonia due to lack of efficacy data.
- The prescribing information of the medicines will be updated with the new indication and a warning against use for prevention of pneumonia.

More about the medicines

Bacterial lysate medicines are made from bacterial cells that are broken down and are intended to stimulate the immune system to recognise and fight infections. These medicines are taken by mouth (as capsules, tablets, granules/powder for making up an oral mixture or drops), dissolved under the tongue (as tablets), inhaled through the nose (as a liquid) or given by injection into a muscle or under the skin.

Bacterial lysate medicines have been authorised via national procedures. They are available in Austria, Belgium, Bulgaria, Czech Republic, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia and Slovenia. They are sold under several brand names including Broncho Munal, Broncho Vaxom, Buccalin, Immubron, Immucytal, Ismigen, Lantigen B, Luivac, Ommunal, Paspap, Pir-05, Polyvaccinum, Provax, Respivax and Ribomunyl.

More about the procedure

The review of bacterial lysate medicines was initiated on 28 June 2018 at the request of Italy, 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.