EMA recommends the use of bacterial lysate medicines only for prevention of recurrent respiratory infections

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Information on bacterial lysate 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.
- Bacterial lysate 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.

In Malta the following products are authorised through national procedures

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Branhamella Catarrhalis 39.9 antigen unit(s)/millilitre | Haemophilus Influenzae B 50.2 antigen unit(s)/millilitre | Klebsiella Pneumoniae 39.8 antigen unit(s)/millilitre | Streptococcus Pyogenes 126.2 antigen unit(s)/millilitre | Staphylococcus Aureus 79.6 antigen unit(s)/millilitre | Streptococcus Pneumoniae 63.2 antigen unit(s)/millilitre	Lantigen B	Oral Drops, Suspension	OTC	MA016/00101	Bruschettini S.r.L.
Lyophilized Bacterial Lysates 50 milligram(s)	Immubron	Tablet	POM	MA016/00401	Bruschettini S.r.L.

Information from the EMA about the efficacy in preventing recurrent respiratory tract infection

Data collected from the review showed effectiveness of these medicines in the prevention of recurrent respiratory tract infections and the safety profile in line with what is expected from these types of products. Committee for Medicinal Products for Human Use's (CHMP) recommendations are:

- Bacterial lysate medicines authorised for respiratory conditions should only be used for the prevention of recurrent respiratory infections, except for 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
- The use of bacterial lysate medicines can continue but the companies must provide further data on safety and effectiveness from new clinical studies by 2026.

A European Commission decision on this opinion will be issued in due course.

In Malta

For Healthcare Professionals

- The indications of bacterial lysate medicines are being restricted to prophylaxis of recurrent respiratory tract infections, except for 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.

Advice 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.

For more information visit the European Medicines Agency's Bacterial lysate medicines press release.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on bacterial lysate medicines. 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
Medicines Authority

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

Feedback Form

The 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 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

Medicines Authority

Sir Temi Żammit Buildings

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