Bacterial lysate medicines for respiratory conditions: EMA's assessment to include recent data on effectiveness

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Information on bacterial lysate medicines

- Bacterial lysate medicines are used on their own or with other medicines to treat or prevent upper or lower respiratory tract infections or for the treatment of chronic respiratory conditions including chronic bronchitis (inflammation of the airways in the lungs) and chronic obstructive pulmonary disease (damage or blockage of the airways and air sacs in the lungs).
- Bacterial lysate medicines are made from bacterial cells that are broken down and are intended to stimulate the immune system to recognise and fight bacterial 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), or inhaled through the nose (as a liquid).

In Malta the following product is authorised through a national procedure

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Branhamella Catarrhalis Haemophilus Influenzae B Klebsiella Pneumoniae Streptococcus Pyogenes Staphylococcus Aureus Streptococcus Pneumoniae	Lantigen B	Oral drops, suspension	OTC	MA016/00101	Bruschettini S.r.l

Information from the EMA about the effectiveness of bacterial lysate medicines

The Committee for Medicinal Products for Human Use (CHMP) started a review of bacterial lysate medicines at the request of the Italian medicines Agency (AIFA), under Article 31 of Directive 2001/83/EC.

Recent studies have cast doubt on the effectiveness of bacterial lysate medicines in reducing the number and severity of respiratory infections in adults and children who experience repeated

infections. In addition, in very rare cases, these medicines are known to cause serious side effects related to the immune system (the body's natural defences).

The EMA will now review the available information and recommend whether the marketing authorisations for the medicines should be maintained, varied or suspended across the EU.

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

For more information please see the European Medicines Agency's bacterial lysate medicines referral page

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 (available from: http://www.medicinesauthority.gov.mt/adrportal) and sent by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or email to postlicensing.medicinesauthority@gov.mt 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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by the Licensee

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

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