EMA completes review of inhaled corticosteroids for chronic obstructive pulmonary disease

Review finds no differences between products in risk of pneumonia

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Information on Inhaled Corticosteroids (ICS)

- Corticosteroids are anti-inflammatory medicines used for a wide range of conditions including Chronic Obstructive Pulmonary Disorder (COPD).
- COPD is a chronic inflammatory disease of the lungs in which the airways and air sacs in the lungs become damaged or blocked.
- Inhaled corticosteroids (ICS) cause a reduction in lung inflammation and facilitate breathing.
- In Europe beclomethasone, budesonide, flunisolide, fluticasone propionate and fluticasone furoate are the corticosteroids authorised and marketed as inhalation formulations (either alone or in combination with beta-2 agonists) for use in COPD.

Information on the EMA's completed review of inhaled corticosteroids for chronic obstructive pulmonary disease.

The EMA has completed a review (see safety circular P18/2015) of the known risk of pneumonia (lung infection) in patients who take inhaled corticosteroid medicines to treat chronic obstructive pulmonary disease (COPD),

- The review confirmed the risk of pneumonia with these products, which has been known for many years, and that it is common (can affect between 1 and 10 COPD patients in 100 using these medicines).
- The review did not find any conclusive evidence of differences in this risk for different products.
- Overall the benefits of inhaled corticosteroid medicines in treating COPD continue to outweigh their risks and there should be no change to the way in which these medicines are used.
- Patients with COPD and their doctors should however be alert for signs and symptoms of pneumonia, bearing in mind that the clinical features of pneumonia overlap with those of a worsening (exacerbation) of the underlying disease.

The review was carried out by the Agency's Pharmacovigilance Risk Assessment Committee (PRAC), which recommended that the product information for these medicines should be updated to adequately

reflect current knowledge about the risks. The PRAC recommendations were sent to the Committee for Medicinal Products for Human Use (CHMP), which has now adopted the Agency's opinion.

In Malta

For Healthcare Professionals

Following a review of the available data, EMA has confirmed the risk of pneumonia with inhaled corticosteroids (ICS) in patients with COPD. Healthcare Professionals are encouraged to be aware that:

- There is no conclusive clinical evidence for intra-class differences in the magnitude of the risk among ICS products.
- There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.
- The product information for all medicines of the class will be updated to reflect current knowledge about pneumonia risk.
- Healthcare professionals should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.
- Patients should be advised to report any increased breathing difficulties or other symptoms suggestive of infection.
- The Agency's review included published data from randomised controlled clinical trials and a number of meta-analyses, as well as observational studies. No clinical trials directly examined the risk of pneumonia with ICS head to head, and only indirect comparison in meta-analyses/systematic reviews or from observational studies is available. Due to the variability in the clinical data and multiple uncertainties with study methodologies, this does not provide conclusive evidence for intra-class differences in the magnitude of risk.

For Patients

It has been known for some time that inhaled corticosteroid medicines increase the risk of pneumonia (infections of the lungs) in patients taking these medicines for the long-term lung disease COPD (chronic obstructive pulmonary disease). Patients are encouraged to be aware that;

- Corticosteroid inhalers reduce inflammation and swelling in the lungs and so help breathing in patients with COPD.
- EMA has reviewed the risk of pneumonia in COPD patients using corticosteroid inhalers and has concluded that this risk applies to all medicines of this class. The evidence did not confirm any differences in risk between products.

- Patients need to alert their doctors if they start to get symptoms that suggest they are developing pneumonia, so that it can be identified and treated early. These symptoms can be like those of an exacerbation (an episode of worsening COPD) and include fever or chills, increased amounts of mucus (phlegm) or a change in its colour, or worsening of cough or breathing difficulties.
- Patients who have any concerns should discuss them with their doctor or other healthcare professional. They should not stop using their inhaler or change the way they use it without consulting their prescriber.

For more information on the review of inhaled corticosteroids please refer to the European Medicines Agency's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on inhaled corticosteroids . 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.

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 it together with this document (address side up), stapling the ends and then posting (no stamp required)

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Pharmacovigilance Section

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Sir Temi Żammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000