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PRAC reviews known risk of pneumonia with inhaled corticosteroids for chronic obstructive pulmonary disease

Review finds no differences in this risk between products

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has reviewed the known risk of pneumonia (infection of the lungs) with inhaled corticosteroid-containing medicines when used to treat chronic obstructive pulmonary disease (COPD). COPD is a long-term disease of the lungs in which the airways and air sacs in the lungs become damaged or blocked, leading to breathing difficulties. Corticosteroids are widely used in the European Union (EU) to treat COPD and are usually taken by inhalation using an inhaler device.

The PRAC review confirms that COPD patients treated with inhaled corticosteroids are at increased risk of pneumonia; however the Committee's view is that the benefits of inhaled corticosteroids continue to outweigh their risks. The PRAC also looked whether there were any differences in the risk of pneumonia between these products, and did not find conclusive evidence of such difference. Pneumonia remains a common side effect for all of them.

An update of the product information is being recommended to adequately reflect the current knowledge. There is no change to the way these medicines should be used; however, doctors and patients should be vigilant for signs and symptoms of pneumonia in patients with COPD as the clinical features of pneumonia overlap with those of exacerbations of the underlying disease.

The PRAC recommendation will now be forwarded to the Committee for Medicinal Products for Human Use (CHMP) for the adoption of EMA's final opinion. Further details including advice for patients and healthcare professionals will be published at the time of the CHMP opinion.

More about the medicine

Corticosteroids, also known as steroids, are anti-inflammatory medicines used for a wide range of conditions. They are similar to natural hormones normally produced by the adrenal glands (two small glands located above the kidneys). When taken by inhalation they attach to receptors in the airways and cause a reduction in lung inflammation, which makes breathing easier. They are usually taken via inhalers which either contain a corticosteroid alone or a corticosteroid in combination with another medicine (such as a long-acting beta₂ agonist that widens the airways). Beclomethasone, budesonide,



flunisolide, fluticasone propionate and fluticasone furoate are corticosteroids authorised and marketed as inhalation formulations for use in COPD. Corticosteroid-containing medicines have been authorised in the EU through both central and national approval procedures.

More about the procedure

The review was initiated at the request of the European Commission on 7 May 2015, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's final opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.

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