
Start of review of inhaled corticosteroids for chronic obstructive pulmonary disease

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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 beta2 agonists) for use in COPD. For more details on authorised ICS products in Malta refer to Annex 1 at the end of this document).

Information from European Medicines Agency about the risk of pneumonia with inhaled corticosteroids in COPD patients

The EMA has requested a review to evaluate the risk of pneumonia when ICS are used for COPD;

The risk of pneumonia with these medicines is known and was first identified in 2007 when a study showed that patients treated with an inhaled corticosteroid (fluticasone) were at higher risk of developing pneumonia than those given placebo. New studies of individual inhaled corticosteroids and combined study results (meta-analyses) on the class of inhaled corticosteroids have provided further data on the risk of pneumonia. EMA will now review all available data on the risk of pneumonia with inhaled corticosteroids for COPD and consider the need to update the existing prescribing advice across the EU.

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

In Malta

For Healthcare Professionals and Patients

Healthcare Professionals are encouraged to refer to the product information when prescribing inhaled corticosteroids for COPD. Such information can be accessed from the Medicines Authority's website by searching for the product in the [online database](#).

Patients should continue to take their medicines as prescribed. Patient who have any questions about their COPD medicine are encouraged to discuss them with their healthcare professional.

For more information on this issue 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 corticosteroid containing medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending to <http://www.medicinesauthority.gov.mt/adrportal> or online at <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

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.

Annex 1: Table of Inhaled corticosteroid containing products authorised in Malta

Active Ingredients	Product name	Pharmaceutical form	Classification	Authorisation number	MAH/license holder
Budesonide 160µg /Formoterol Fumarate Dihydrate 9µg	Bufomix Easyhaler 160/4.5	Inhalation powder	POM	MA624/00102	Orion corporation
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Bufomix Easyhaler 320/9	Inhalation powder	POM	MA624/00103	Orion corporation
Budesonide 160µg/Formoterol Fumarate Dihydrate 4.5µg	Orest Easyhaler 160/4.5	Inhalation powder	POM	MA624/00202	Orion corporation
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Orest Easyhaler 320/9	Inhalation powder	POM	MA624/00203	Orion corporation
Budesonide 160µg/Formoterol Fumarate Dihydrate 4.5µg	Biresp Spiromax 160/4.5	Inhalation powder	POM	EU/1/14/921/001	Teva pharma b.v.
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Biresp Spiromax 320/9	Inhalation powder	POM	EU/1/14/921/004	Teva pharma b.v.
Budesonide 160µg/Formoterol Fumarate Dihydrate 4.5µg	Duosp Spiromax 160/4.5	Inhalation powder	POM	EU/1/14/920/001	Teva pharma b.v.
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Duosp Spiromax 320/9	Inhalation powder	POM	EU/1/14/920/004	Teva pharma b.v.
Budesonide 160µg/Formoterol Fumarate Dihydrate 4.5µg	Vylaer Spiromax 160/4.5	Inhalation powder	POM	EU/1/14/949/001	Teva pharma b.v.
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Vylaer Spiromax 320/9	Inhalation powder	POM	EU/1/14/949/002	Teva pharma b.v.
Budesonide 320µg/Formoterol Fumarate Dihydrate 9µg	Budesonide/Formoterol Teva Pharma B.V. 320/9	Inhalation powder	POM	EU/1/14/948/002	Teva pharma b.v.
Budesonide 160µg/Formoterol Fumarate Dihydrate 4.5µg	Budesonide/Formoterol Teva Pharma B.V. 160/4.5	Inhalation powder	POM	EU/1/14/948/001	Teva pharma b.v.
Budesonide 100µg/Formoterol 6µg	Symbicort Turbohaler 100/6	Inhalation powder	POM	MA046/00901	Astrazeneca ab
Budesonide 200µg/Formoterol 6µg	Symbicort Turbohaler 200/6	Inhalation powder	POM	MA046/00902	Astrazeneca ab

Budesonide 400µg/Formoterol 12µg	Symbicort Turbohaler 400/12	Inhalation powder	POM	MA046/00903	Astrazeneca ab
Budesonide 100µg	Pulmicort Turbohaler 100	Inhalation powder	POM	MA046/01401	Astrazeneca ab
Budesonide 200µg	Pulmicort Turbohaler 200	Inhalation powder	POM	MA046/01402	Astrazeneca ab
Budesonide 200µg	Miflonide 200	Inhalation powder	POM	MA088/02101	Novartis pharmaceuticals uk limited
Budesonide 400µg	Miflonide 400	Inhalation powder	POM	MA088/02102	Novartis pharmaceuticals uk limited
Budesonide 200µg	Frenolyn 200	Inhalation powder	POM	AA032/07401	Medochemie limited
Budesonide 400µg	Frenolyn 400	Inhalation powder	POM	AA032/07402	Medochemie limited
Budesonide 50µg	Budesonide Aldo-Union 50mcg	Pressurised inhalation, suspension	POM	AA158/00301	Lab. Aldo-union s.a.
Budesonide 200µg	Budesonide Aldo-Union 200mcg	Pressurised inhalation, suspension	POM	AA158/00302	Lab. Aldo-union s.a.
Fluticasone Propionate 50µg/Salmeterol 25µg	Seretide Evohaler 25/50	Pressurised inhalation, suspension	POM	AA192/00904	Glaxo smithkline ireland limited
Fluticasone Propionate 100 µg/Salmeterol 50µg	Seretide Diskus 50/100	Inhalation powder	POM	MA192/00901	Glaxo smithkline ireland limited
Fluticasone Propionate 250 µg/Salmeterol 50µg	Seretide Diskus 50/250	Inhalation powder	POM	MA192/00902	Glaxo smithkline ireland limited
Fluticasone Propionate 500 µg/Salmeterol 50µg	Seretide Diskus 50/500	Inhalation powder	POM	MA192/00903	Glaxo smithkline ireland limited
Fluticasone Propionate 50 µg	Flixotide Diskus 50	Inhalation powder	POM	AA192/01601	Glaxo smithkline ireland limited
Fluticasone Propionate 100 µg	Flixotide Diskus 100	Inhalation powder	POM	AA192/01602	Glaxo smithkline ireland limited
Fluticasone Propionate 250 µg	Flixotide Diskus 250	Inhalation powder	POM	AA192/01603	Glaxo smithkline ireland limited
Fluticasone Propionate 50 µg	Flixotide Evohaler 50	Pressurised inhalation, suspension	POM	MA192/00401	Glaxo smithkline ireland limited
Fluticasone Propionate 125 µg	Flixotide Evohaler 125	Pressurised inhalation,	POM	MA192/00402	Glaxo smithkline

		suspension			ireland limited
Fluticasone Propionate 250 µg	Flixotide Evohaler 250	Pressurised inhalation, suspension	POM	MA192/00403	Glaxo smithkline ireland limited
Fluticasone Propionate 250 µg	Fluticapen 250	Inhalation powder	POM	AA228/00901	Elpen pharmaceutical co. Inc.
Fluticasone Propionate 500 µg	Fluticapen 500	Inhalation powder	POM	AA228/00902	Elpen pharmaceutical co. Inc
Fluticasone Propionate 250 µg/Salmeterol 50 µg	Rolenium Inhalation Powder 50/250	Inhalation powder	POM	AA228/01201	Elpen pharmaceutical co. Inc
Fluticasone Propionate 500 µg/Salmeterol 50 µg	Rolenium Inhalation Powder 50/500	Inhalation powder	POM	AA228/01202	Elpen pharmaceutical
Fluticasone Furoate 92 µg/Vilanterol 22 µg	Revinty Ellipta 92/22	Inhalation powder	POM	EU/1/14/929/001	Glaxo group ltd
Fluticasone Furoate 184 µg/Vilanterol 22 µg	Revinty Ellipta 184/22	Inhalation powder	POM	EU/1/14/929/004	Glaxo group ltd
Fluticasone Furoate 92 µg/Vilanterol 22 µg	Relvar Ellipta 92/22	Inhalation powder	POM	EU/1/13/886/001	Glaxo group ltd
Fluticasone Furoate 184 µg/Vilanterol 22 µg	Relvar Ellipta 184/22	Inhalation powder	POM	EU/1/13/886/004	Glaxo group ltd
Salmeterol 50 µg/Fluticasone Propionate 500 µg	Lifsar Pulmojet	Inhalation powder	POM	MA082/08201	Sanofi malta limited
Fluticasone Propionate 125 µg	Truflo 125	Pressurised inhalation, suspension	POM	MA964/00301	Momaja s.r.o.
Fluticasone Propionate 250 µg	Truflo 250	Pressurised inhalation, suspension	POM	MA964/00302	Momaja s.r.o.
Beclometasone Dipropionate 100 µg/Formoterol Fumarate Dihydrate 6 µg	Fostair 100/6	Pressurised inhalation, solution	POM	AA729/09701	Cherubino limited