Union Register support

Public Health - Union Register of medicinal products

Union Register of medicinal products for human use

Product information

Product name:	Trelegy Ellipta	ACTIVE
EU number:	EU/1/17/1236	
Active substance:	fluticasone furoate/umeclidinium/vilanterol	
Indication:	Trelegy Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist (for effects on symptom control and prevention of exacerbations see section 5.1 of the SmPC).	
Marketing Authorisation Holder:	GlaxoSmithKline Trading Services Limited Riverwalk 12, Citywest Business Campus, Dublin 24, Ireland	
ATC:	Anatomical main group: R - Respiratory system Therapeutic subgroup: R03 - Drugs for obstructive airway diseases Pharmacological subgroup: R03A - Adrenergics, inhalants Chemical subgroup: R03AL - Adrenergics in combination with anticholinergics incl. triple combinations with corticosteroids Chemical substance: R03AL08 - vilanterol, umeclidinium bromide and fluticasone furoate (See WHO ATC Index)	

Links to EMA website: EMA - Trelegy Ellipta

Package presentations

Information about presentations can be found in the website of the European Medicines Agency under the section "Product Information".
Likewise, presentations on which there has been a Commission decision are referred in the Summary of Product Characteristics (Annex I to the Commission Decision granting the marketing authorisation) which is available in the Union Register.

European Commission procedures

By clicking on the icon, it is possible to download all the linguistic versions of a specific Decision or Annex in a single package.

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
17 Nov 2017	Centralised - Authorisation	EMEA/H/C/4363	(2017)7744 of 15 Nov 2017			
30 May 2018	Centralised - Variation	EMEA/H/C/IG/931	-			
Updated with:	Decision (2018)7416 of 31 Oct 2018					
06 Nov 2018	Centralised - 2-Monthly update	EMEA/H/C/4363/WS/1369	(2018)7416 of 31 Oct 2018			
22 Jan 2019	Centralised - Variation	EMEA/H/C/IG/1052	-			
Updated with:	Decision (2020)1142 of 21 Feb 2020					
29 Mar 2019	Centralised - Notification	EMEA/H/C/004363/N/0008	-			
Updated with:	Decision (2020)1142 of 21 Feb 2020					
29 Nov 2019	Centralised - Variation	EMEA/H/C/IG1159	-			
Updated with:	Decision (2020)1142 of 21 Feb 2020					

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
25 Feb 2020	Centralised - Yearly update	-	(2020)1142 of 21 Feb 2020			
10 Sep 2020	Centralised - Variation	EMEA/H/C/004363/WS1814/0014	-			

Last updated on 12/02/2021.

14 September 2017
EMA/CHMP/244744/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trelegy Ellipta

fluticasone furoate / umeclidinium / vilanterol

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trelegy Ellipta, intended for the maintenance treatment of adults patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD).

The applicant for this medicinal product is GlaxoSmithKline Trading Services.

Trelegy Ellipta will be available as 92 µg / 55 µg / 22 µg Inhalation powder, pre-dispensed. The active substances of Trelegy Ellipta are fluticasone furoate / umeclidinium / vilanterol, Drugs for obstructive airways disease (ATC code: R03AL08). Both umeclidinium (a long-acting muscarinic receptor antagonist) and vilanterol (a selective long-acting, beta$_2$-adrenergic receptor agonist) act locally to produce bronchodilatation by separate mechanisms . Umeclidinium exerts its bronchodilatory activity by competitively inhibiting the binding of acetylcholine with muscarinic receptors on airway smooth muscle.

Vilanterol stimulates the enzyme catalysing AMP into cyclic AMP leading to relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells.
Fluticasone furoate is a corticosteroid and reduces inflammation .

The benefits with Trelegy Ellipta are its ability to improve lung function (as defined by change from baseline trough FEV$_1$ at Week 24; co-primary endpoint) compared with budesonide/formoterol (BUD/FOR) 400 /12 micrograms administered twice-daily in moderate to severe patients not adequately controlled with corticosteroid and long acting B agonist.

The most common side effects are nasopharyngitis (7%), upper respiratory tract infection (2%) and headache (5%).

The full indication is:

Trelegy Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist (for effects on symptom control see section 5.1).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.