Union Register support

Public Health - Union Register of medicinal products

Union Register of medicinal products for human use

Product information

Product name:	Relvar Ellipta	✔ ACTIVE
EU number:	EU/1/13/886	
Active substance:	fluticasone furoate/vilanterol	
Indication:	Asthma Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists. • patients already adequately controlled on both inhaled corticosteroid and long-acting beta2-agonist. COPD (Chronic Obstructive Pulmonary Disease) Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	
Marketing Authorisation Holder:	GlaxoSmithKline (Ireland) Limited 12 Riverwalk, 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: R03AK - Adrenergics and other anti-asthmatics Chemical substance: R03AK10 - vilanterol and fluticasone furoate (See WHO ATC Index)
Links to EMA website:	EMA - Relvar 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

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
14 Nov 2013	Centralised - Authorisation	EMEA/H/C/2673	(2013) 8089 of 13 Nov 2013	-	-	-
20 May 2014	Corrigendum	-	(2014) 3419 of 16 May 2014		-	
22 May 2014	Centralised - Notification	EMEA/H/C/2673/N/4	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					
20 Nov 2014	Centralised - Variation	EMEA/H/C/2673/IG/496	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
18 Dec 2014	Centralised - Variation	EMEA/H/C/2673/WS/602	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					
23 Apr 2015	Centralised - Variation	EMEA/H/C/2673/WS/713/G	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					
25 Jun 2015	Centralised - Variation	EMEA/H/C/2673/WS/694	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					
24 Sep 2015	Centralised - Variation	EMEA/H/C/2673/WS/772	-			
Updated with:	Decision (2015)7838 of 06 Nov 2015					
10 Nov 2015	Centralised - Yearly update	-	(2015) 7838 of 06 Nov 2015	-	-	-
17 Dec 2015	Centralised - Variation	EMEA/H/C/2673/WS/850	-			
Updated with:	Decision (2016)4085 of 24 Jun 2016					
14 Jan 2016	Centralised - Variation	EMEA/H/C/2673/WS/863/G	-			
Updated with:	Decision (2016)4085 of 24 Jun 2016					
28 Jun 2016	Referral	EMEA/H/A-31/1415/C/2673/14	(2016) 4085 of 24 Jun 2016	-	-	-
13 Oct 2016	Centralised - Variation	EMEA/H/C/2673/WS/1025	-			
Updated with:	Decision (2017)6508 of 21 Sep 2017					

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
21 Apr 2017	Centralised - Variation	EMEA/H/C/2673/WS/1030	-			
Updated with:	Decision (2017)6508 of 21 Sep 2017					
21 Apr 2017	Centralised - Variation	EMEA/H/C/2673/WS/992/G	-			
Updated with:	Decision (2017)6508 of 21 Sep 2017					
21 Apr 2017	Centralised - Variation	EMEA/H/C/2673/WS/1101	-			
Updated with:	Decision (2017)6508 of 21 Sep 2017					
18 May 2017	Centralised - Variation	EMEA/H/C/2673/WS/1157	-			
Updated with:	Decision (2017)6508 of 21 Sep 2017					
14 Sep 2017	Centralised - Variation	EMEA/H/C/2673/WS/1224	-			
Updated with:	Decision (2018)1477 of 05 Mar 2018					
25 Sep 2017	Centralised - Yearly update	-	(2017) 6508 of 21 Sep 2017	-	-	-
07 Mar 2018	Centralised - 2-Monthly update	EMEA/H/C/2673/WS/1208	(2018) 1477 of 05 Mar 2018	-	-	-
14 Jun 2018	Centralised - Variation	EMEA/H/C/2673/WS/1343	-			
Updated with:	Decision (2018)8928 of 12 Dec 2018					
03 Jul 2018	Corrigendum	-	(2013) 8089 of 13 Nov 2013		-	
	Centralised - Renewal	EMEA/H/C/2673/R/37	(2018) 5106 of	-	-	-

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
30 Jul 2018			26 Jul 2018			
13 Sep 2018	Centralised - Variation	EMEA/H/C/2673/WS/1449	-			
Updated with:	Decision (2018)8928 of 12 Dec 2018					
14 Dec 2018	Centralised - Transfer Marketing Authorisation Holder	EMEA/H/C/2673/T/40	(2018) 8928 of 12 Dec 2018	-	-	-
16 Jan 2019	Centralised - Variation	EMEA/H/C/IG/1016	-			

Last updated on 11/07/2019.