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Public Health - Union Register of medicinal products

[Union Register of medicinal products for human use](#)

Product information



Product name:	Combivir 	✓ ACTIVE
EU number:	EU/1/98/058	
Active substance:	lamivudine / zidovudine	
Indication:	Combivir is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection	
Marketing Authorisation Holder:	ViiV Healthcare BV Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Nederland	
ATC:	Anatomical main group: J - General antiinfectives for systemic use Therapeutic subgroup: J05 - Antivirals for systemic use Pharmacological subgroup: J05A - Agents affecting the virus directly Chemical subgroup: J05AR - Antivirals for treatment of hiv infections, combinations Chemical substance: J05AR01 - zidovudine and lamivudine (See WHO ATC Index)	
Links to EMA website:	EMA - Combivir	

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			
19 Mar 1998	Centralised - Authorisation	EMEA/H/C/190	(1998) 695 of 18 Mar 1998	-	↓	-	↓		
18 Aug 1998	Centralised - Notification	EMEA/H/C/190/N/1	(1998) 2523 of 17 Aug 1998	-	↓	-	↓		
19 Aug 1998	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/5	-						
19 Aug 1998	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/2-4	-						
20 Oct 1999	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/7-9	-						
16 Nov 1999	Centralised - Variation	EMEA/H/C/190/II/6	(1999) 3716 of 16 Nov 1999	-	↓	-	↓		
28 Dec 2000	Centralised - Variation	EMEA/H/C/190/II/10	(2000) 4281 of 27 Dec 2000	-	↓	-	↓		
		EMEA/H/C/190/II/11		-	↓				

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
02 Aug 2001	Centralised - Variation		(2001) 2051 of 31 Jul 2001		-  ↓	-  ↓
13 Mar 2002	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/13	-			
15 May 2002	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/14	-			
27 Aug 2002	Centralised - Variation	EMEA/H/C/190/II/12	(2002) 3184 of 22 Aug 2002	- ↓	-  ↓	-  ↓
29 Aug 2002	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/15	-			
13 Jun 2003	Centralised - Renewal	EMEA/H/C/190/R/16	(2003) 1896 of 11 Jun 2003	- ↓	-  ↓	-  ↓
23 Jul 2003	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/19	-			
20 Aug 2003	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/18	-			
20 Aug 2003	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/20	-			
16 Jan 2004	Centralised - Variation	EMEA/H/C/190/II/22	(2004) 90 of 14 Jan 2004	- ↓	-  ↓	-  ↓
		EMEA/H/C/190/II/21		- ↓		

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
09 Feb 2004	Centralised - Variation		(2004) 411 of 05 Feb 2004		- 	- 
10 Feb 2004	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IB/25	-			
10 Mar 2004	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/27	-			
01 Jun 2004	Centralised - Variation	EMEA/H/C/190/II/26	(2004) 1982 of 26 May 2004	- 	- 	- 
30 Jul 2004	Centralised - Variation	EMEA/H/C/190/IA/28	-			
Updated with:		Decision (2005)24 of 05 Jan 2005				
07 Sep 2004	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/29	-			
07 Dec 2004	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IB/30	-			
07 Jan 2005	Centralised - Variation	EMEA/H/C/190/II/31	(2005) 24 of 05 Jan 2005	- 	- 	- 
09 Jan 2005	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IB/35	-			
15 Jun 2005	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/32	-			

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
14 Sep 2005	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/33	-			
12 Dec 2005	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/36	-			
10 Jan 2006	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IB/34	-			
19 Jul 2006	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/37	-			
19 Jul 2006	Centralised - Variation	EMEA/H/C/190/IA/38	-			
Updated with:		Decision (2007)313 of 26 Jan 2007				
27 Jul 2006	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/40	-			
13 Sep 2006	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IB/39	-			
30 Jan 2007	Centralised - Variation	EMEA/H/C/190/II/41	(2007) 313 of 26 Jan 2007	-	↓	↓
20 Feb 2007	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/46	-		↓	↓
28 Feb 2007	Centralised - Variation	EMEA/H/C/190/IA/47	-			↓

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
Updated with:		Decision (2007)4189 of 03 Sep 2007				
01 Mar 2007	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/42	-			
05 Sep 2007	Centralised - Variation	EMEA/H/C/190/II/48	(2007) 4189 of 03 Sep 2007	-	↓	↓
						
16 Nov 2007	Centralised - Variation	EMEA/H/C/190/II/43	(2007) 5599 of 13 Nov 2007	-	↓	↓
						
27 Nov 2007	Centralised - Variation	EMEA/H/C/190/II/44	(2007) 5844 of 23 Nov 2007	-	↓	↓
						
29 Jan 2008	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/II/50	-			
15 Feb 2008	Centralised - Renewal	EMEA/H/C/190/R/49	(2008) 682 of 13 Feb 2008	-	↓	↓
						
29 Jul 2008	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/52	-			
29 Jul 2008	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/54	-			
29 Jul 2008	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/190/IA/53	-			
18 Sep 2008	Centralised - Variation	EMEA/H/C/190/II/51	(2008) 5251 of 16 Sep 2008	-	↓	↓
						

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes			
04 Apr 2009	Centralised - Variation	EMEA/H/C/190/II/55	(2009) 2697 of 02 Apr 2009	-	↓	-	↓	-	↓
28 Jan 2010	Centralised - Variation	EMEA/H/C/190/II/56	(2010) 529 of 25 Jan 2010	-	↓	-	↓	-	↓
12 May 2010	Centralised - Transfer Marketing Authorisation Holder	EMEA/H/C/190/T/57	(2010) 3159 of 10 May 2010	-	↓	-	↓	-	↓
09 Sep 2010	Centralised - Notification	EMEA/H/C/190/N/58	-						
Updated with:		Decision (2010)7738 of 03 Nov 2010							
09 Nov 2010	Centralised - Variation	EMEA/H/C/190/II/60	(2010) 7738 of 03 Nov 2010	-	↓	-	↓	-	↓
04 May 2011	Centralised - Variation	EMEA/H/C/190/II/59	(2011) 3083 of 02 May 2011	-	↓	-	↓	-	↓
28 Mar 2013	Centralised - 2-Monthly update	EMEA/H/C/190/WS/338	(2013) 1903 of 26 Mar 2013	-	↓	-	↓	-	↓
29 May 2013	Centralised - 2-Monthly update	EMEA/H/C/190/WS/361	(2013) 3237 of 27 May 2013	-	↓	-	↓	-	↓
27 Nov 2013	Centralised - Notification	EMEA/H/C/190/N/74	-						
Updated with:		Decision (2015)2741 of 20 Apr 2015							
25 Apr 2014	Centralised - Variation	EMEA/H/C/190/WS/544	-						
Updated with:		Decision (2015)2741 of 20 Apr 2015							
		-	(2015) 2741 of	-	↓	-	↓	-	↓

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
22 Apr 2015	Centralised - Yearly update		20 Apr 2015			
23 Apr 2015	Centralised - Variation	EMA/H/C/190/WS/645	-			
Updated with:		Decision (2016) 2828 of 02 May 2016				
08 Jul 2015	Centralised - Variation	EMA/H/C/190/IAIN/84	-			
Updated with:		Decision (2016) 2828 of 02 May 2016				
17 Sep 2015	Centralised - Variation	EMA/H/C/190/WS/755	-			
Updated with:		Decision (2016) 2828 of 02 May 2016				
28 Jan 2016	Centralised - Variation	EMA/H/C/190/WS/888/G	-			
Updated with:		Decision (2016) 2828 of 02 May 2016				
01 Apr 2016	Centralised - Variation	EMA/H/C/190/WS/769	-			
Updated with:		Decision (2017) 1607 of 03 Mar 2017				
04 May 2016	Centralised - Yearly update	-	(2016) 2828 of 02 May 2016	-	↓	-
					↓	↓
						
19 Jul 2016	Centralised - Variation	EMA/H/C/190/IB/89	-			
Updated with:		Decision (2017) 1607 of 03 Mar 2017				
07 Mar 2017	Centralised - Yearly update	-	(2017) 1607 of 03 Mar 2017	-	↓	-
					↓	↓
						
25 Jan 2018	Centralised - Variation	EMA/H/C/190/WS/1156	-			

Close date	Procedure type	EMA number	Decision number	Summary	Decisions	Annexes
Updated with:		Decision (2019)858 of 31 Jan 2019				
28 Sep 2018	Centralised - Variation	EMEA/H/C/190/IAIN/93	-			
Updated with:		Decision (2019)858 of 31 Jan 2019				
04 Feb 2019	Centralised - Transfer Marketing Authorisation Holder	EMEA/H/C/190/T/94	(2019) 858 of 31 Jan 2019	-	↓	-
					↓	↓
					↓	↓
11 Jun 2020	Centralised - Variation	EMEA/H/C/IG1237	-			
03 Dec 2020	Centralised - Variation	EMEA/H/C/000190/WS1951/0098	-			

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