

Community register of m x

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PHARMACEUTICALS - COMMUNITY REGISTER

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**AUTHORISED**

Community register of medicinal products for human use

**Product information**

Invented name:	<b>Ventavis</b>
Auth. number :	<b>EU/1/03/255</b>
Active substance :	<b>Iloprost</b>

Orphan market exclusivity for "Treatment of primary and of the following forms of secondary pulmonary hypertension: connective tissue disease pulmonary hypertension, drug-induced pulmonary hypertension, portopulmonary hypertension, pulmonary hypertension associated with congenital heart disease, chronic thromboembolic

Community register of medicinal products

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Orphan market exclusivity for "Treatment of primary and of the following forms of secondary pulmonary hypertension: connective tissue disease pulmonary hypertension, drug-induced pulmonary hypertension, portopulmonary hypertension, pulmonary hypertension associated with congenital heart disease, chronic thromboembolic pulmonary hypertension" (based on designation [EU/3/00/014](#)) started on 18/09/2003  
10 years of market exclusivity  
This orphan market exclusivity has ended on 18/09/2013

ATC:	<b>Anatomical main group: B - Blood and blood forming organs Therapeutic subgroup: B01 - Antithrombotic agents Pharmacological subgroup: B01A - Antithrombotic agents Chemical subgroup: B01AC - Platelet aggregation inhibitors excluding Heparin Chemical substance: B01AC11 - cloricromen (See WHO ATC Index)</b>
Indication:	<b>Treatment of patients with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms.</b>
Marketing Authorisation Holder:	<b>Bayer Pharma AG D-13342 Berlin, Deutschland</b>
EPAR and active package presentations*	

## Package presentations

Community register of medicines

ec.europa.eu/health/documents/community-register/html/h255.htm

## 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 Community Register.

## European Commission procedures

Close date procedure	Procedure type	EMA number	Decision	summary publication	decision docs	annex
18/09/2003	Centralised - Authorisation	EMA/H/C/474	(2003)3348 of 16/09/2003	sum	dec	anx
16/04/2004	Centralised - Notification	EMA/H/C/474/N/1	(2004)1486 of 13/04/2004	sum	dec	anx
14/10/2004	Centralised - Notification	EMA/H/C/474/N/2				
	Updated with Decision(2005)660 of 07/03/2005					
25/11/2004	Centralised - Notification	EMA/H/C/474/N/4				
	Updated with Decision(2005)3436 of 05/09/2005					

Date	Decision Type	Reference	Summary	Decision Date
25/11/2004	Centralised - Notification	EMEA/H/C/474/N/4		
	Updated with Decision(2005)3436 of 05/09/2005			
9/03/2005	Centralised - Annual reassessment	EMEA/H/C/474/S/3	(2005)660 of 7/03/2005	sum ▾ dec ▾ anx ▾
8/09/2005	Centralised - Variation	EMEA/H/C/474/II/5	(2005)3436 of 5/09/2005	sum ▾ dec ▾ anx ▾
4/05/2006	Centralised - Variation	EMEA/H/C/474/II/6	(2006)1884 of 2/05/2006	sum ▾ dec ▾ anx ▾
1/06/2006	Centralised - Annual reassessment	EMEA/H/C/474/S/7		
12/06/2006	Centralised - Variation	EMEA/H/C/474/II/8	(2006)2303 of 8/06/2006	sum ▾ dec ▾ anx ▾
27/09/2006	Centralised - Variation (no change in Commission Decision)	EMEA/H/C/474/II/9		
29/01/2007	Centralised - Annual reassessment	EMEA/H/C/474/S/10		
10/04/2007	Centralised - Variation	EMEA/H/C/474/IA/12		
	Updated with Decision(2007)2347 of 30/05/2007			
1/06/2007	Centralised - Variation	EMEA/H/C/474/II/11	(2007)2347 of 30/05/2007	sum ▾ dec ▾ anx ▾
4/10/2007	Centralised - Notification	EMEA/H/C/474/N/13		

Date	Decision Type	Reference	Summary
4/10/2007	Centralised - Notification	EMA/H/C/474/N/13	
16/01/2008	Updated with Decision(2008)4111 of 28/07/2008		
16/01/2008	Centralised - Variation	EMA/H/C/474/IA/16	
24/01/2008	Updated with Decision(2008)4111 of 28/07/2008		
24/01/2008	Centralised - Annual reassessment	EMA/H/C/474/S/15	
31/03/2008	Centralised - Variation (no change in Commission Decision)	EMA/H/C/474/II/17	
20/06/2008	Centralised - Variation	EMA/H/C/474/IA/21	
30/07/2008	Updated with Decision(2008)4111 of 28/07/2008		
30/07/2008	Centralised - Variation	EMA/H/C/474/II/19, 20	(2008)4111 of 28/07/2008
4/09/2008	Centralised - Renewal	EMA/H/C/474/R/18	sum ▾ dec ▾ anx ▾
31/10/2008	Centralised - Variation	EMA/H/C/474/IA/24	(2008)4951 of 2/09/2008
	Updated with Decision(2009)4240 of 27/05/2009		sum ▾ dec ▾ anx ▾

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