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Medicinal products for human use

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Community register of medicinal products for human use

Product information

Invented name:	Ventavis
INN :	Iloprost
	N.B. This substance has prior been designated as orphan under number EU/3/00/014

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Product information

Invented name:	Ventavis
INN :	Iloprost
ATC:	N.B. This substance has prior been designated as orphan under number EU/3/00/014
Indication:	B - Blood and blood forming organs B01 - Antithrombotic agents B01A - Antithrombotic agents B01AC - Platelet aggregation inhibitors excl. Heparin B01AC11 - Iloprost (See WHO ATC Index) Treatment of patients with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms
Marketing Authorisation Holder:	Bayer Schering Pharma AG

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Package presentations

EU Number	Presentation	Authorisation

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Package presentations

EU Number	Presentation	Authorisation date
EU/1/03/2 55/001	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - Ampoule (glass) - 2 ml (10 µg/ml) - 30 ampoules	16 Sep 2003
EU/1/03/2 55/002	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - Ampoule (glass) - 2 ml (10 µg/ml) - 100 ampoules	16 Sep 2003
EU/1/03/2 55/003	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - Ampoule (glass) - 2 ml (10 µg/ml) - 300 ampoules	16 Sep 2003
EU/1/03/2 55/004	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - ampoule (glass) - 1 ml (10 µg/ml) - 30 ampoules	02 May 2006
EU/1/03/2 55/005	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - ampoule (glass) - 1 ml (10 µg/ml) - 168 ampoules	02 May 2006
EU/1/03/2 55/006	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - ampoule (glass) - 2 ml (10 µg/ml) - 90 ampoules	28 Jul 2008
EU/1/03/2 55/007	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - ampoule (glass) - 2 ml (10 µg/ml) - 3 x 30 ampoules	27 May 2009
EU/1/03/2 55/008	Ventavis - 10 µg/ml - Nebuliser solution - Inhalation use - ampoule (glass) - 2 ml (10 µg/ml) - 10 x 30 ampoules	27 May 2009

European Commission procedures

Close date procedure	Procedure type	EMA number	Decision	summary publications	decision documents	annex
18/09/2003	Centralised - Authorisation of an orphan medicinal product under exceptional circumstances	EMA/H/C/47/4	C(2003)3348 of 16/09/2003	sum	dec	anx
16/04/2004	Centralised - Notification - (Art. 61(3) Dir 2001/83) normal	EMA/H/C/47/4/N/1	C(2004)1486 of 13/04/2004	sum	dec	anx
	Will be updated later					
14/10/2004	Centralised - Notification 61(3) - (Acceptance modification)	EMA/H/C/47/4/N/2				
	Updated with Decision C(2005)660 of 7/03/2005					
25/11/2004	Centralised - Notification 61(3) - (Acceptance modification)	EMA/H/C/47/4/N/4				
	Updated with Decision C(2005)3436 of 5/09/2005					
9/03/2005	Centralised - Annual reassessment	EMA/H/C/47/4/S/3	C(2005)660 of 7/03/2005	sum	dec	anx

European Commission procedures*

9/03/2005	Centralised - Annual reassessment	EMA/H/C/47 4/S/3	C(2005) 660 of 7/03/2005	sum	dec	anx
8/09/2005	Centralised - Variation Type II - (Acceptance modification)	EMA/H/C/47 4/II/5	C(2005) 3436 of 5/09/2005	sum	dec	anx
4/05/2006	Centralised - Variation Type II - (Additional pack size)	EMA/H/C/47 4/II/6	C(2006) 1884 of 2/05/2006	sum	dec	anx
1/06/2006	Centralised - Annual reassessment	EMA/H/C/47 4/S/7				
12/06/2006	Centralised - Variation Type II - (Acceptance modification)	EMA/H/C/47 4/II/8	C(2006) 2303 of 8/06/2006	sum	dec	anx
27/09/2006	Centralised - Variation Type II - No decision, letter of acceptance only	EMA/H/C/47 4/II/9				
29/01/2007	Centralised - Annual reassessment	EMA/H/C/47 4/S/10				
10/04/2007	Centralised - Variation Type IAIN - (Acceptance modification)	EMA/H/C/47 4/IA/12				
	Updated with Decision C(2007)2347 of 30/05/2007					
1/06/2007	Centralised - Variation Type II - (Acceptance modification)	EMA/H/C/47 4/II/11	C(2007) 2347 of	sum	dec	anx

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