

**Summary of Community decisions on marketing authorizations in respect of medicinal products  
from 1.10.2006 to 31.10.2006**

*(Decisions taken pursuant to Article 34 of Directive 2001/83/EC <sup>(1)</sup> or Article 38 of Directive 2001/82/EC <sup>(2)</sup>)*

(2006/C 287/04)

**— Issuing, maintenance or modification of a national marketing authorisation**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	Member State concerned	Date of notification
11.10.2006	Doxastad (doxazosin) Art 29	See Annex I	See Annex I	13.10.2006
11.10.2006	Doxazosin Winthrop (doxazosin) Art 29 -	See Annex II	See Annex II	13.10.2006
11.10.2006	Cardoreg (doxazosin) Art 29	See Annex III	See Annex III	13.10.2006
11.10.2006	Doxagamma (doxazosin) Art 29	See Annex IV	See Annex IV	13.10.2006
11.10.2006	Doxazosin Retard Arrow (doxazosin) Art 29	See Annex V	See Annex V	13.10.2006
13.10.2006	Cobactan DC Art 39	See Annex VI	See Annex VI	16.10.2006

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(2)</sup> OJ L 311, 28.11.2001, p. 1.

## ANNEX I

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),  
ROUTE(S) OF ADMINISTRATION, APPLICANT(S) MARKETING AUTHORISATION HOLDER(S) IN THE  
MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia		STADA Arzneimittel AG Stadastr. 2-18, D-61118 Bad Vilbel Tél: 0049 6101 603301 Fax: 0049 6101 603151	Doxalfa 4 mg toimeainet prolongeeritult vabastavad tabletid	4 mg	Prolonged-release tablet	Oral
Latvia		STADA Arzneimittel AG Stadastr. 2-18, D-61118 Bad Vilbel Tél: 0049 6101 603301 Fax: 0049 6101 603151	Doxalfa 4 mg ilgstošās darbības tabletes	4 mg	Prolonged-release tablet	Oral
Lithuania		STADA Arzneimittel AG Stadastr. 2-18, D-61118 Bad Vilbel Tél: 0049 6101 603301 Fax: 0049 6101 603151	Doxalfa 4 mg pailginto atpa- laidavimo tabletės	4 mg	Prolonged-release tablet	Oral
Netherlands		Cerntfarm Services B.V. Nieuwe Donk 9 4879 AC Etten-Leur Nederland Tél: 0031 765 081000 Fax: 0031 765 035614	Doxazosine retard CF 4mg, tabletten met gereguleerde afgifte	4 mg	Prolonged-release tablet	Oral
Spain		Laboratorio STADA, S.L. Frederic Mompou, 5 08960 Sant Just Desvern E-Barcelone Tél: 0034 93 47 38889 Fax: 0034 93 47 37495	DOXAZOSINA NEO STADA 4 mg comprimidos de libera- ción prolongada EEG	4 mg	Prolonged-release tablet	Oral
Sweden	STADA Arzneimittel AG Stadastr. 2-18, D.61118 Bad Vilbel Tél: 0049 6101 603301 Fax: 0049 6101 603151		Doxastad 4mg depottablett	4 mg	Prolonged-release tablet	Oral
United Kingdom		Genus Pharmaceuticals Benham Valence, Speen Newbury Berkshire RG20 8LU United Kingdom Tél: 01635 568400 Fax: 01635 568401	Doxadura XL 4 mg	4 mg	Prolonged-release tablet	Oral

## ANNEX II

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),  
ROUTE(S) OF ADMINISTRATION, APPLICANT(S) MARKETING AUTHORISATION HOLDER(S) IN THE  
MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	Name	Strength	Pharmaceutical Form	Route of administration
Denmark	Winthrop Pharmaceuticals UK Ltd 1 Onslow Street Guildford Surrey GU1 4YS Royaume-Uni Tél: 00 44 (0) 1483 55 48 31 Fax: 00 44 (0) 1483 55 48 31		Doxazosin 'Winthrop'	4 mg	Prolonged release tablets	Oral
Germany		Winthrop Arzneimittel GmbH Industriestrasse 10 82256 D-Furstenfeldbruck Tél: 0049 (0) 81 41 3572 324 Fax: 0049 (0) 81 41 3572 329	Doxazosin Winthrop 4 mg Retardtabletten	4 mg	Prolonged release tablets	Oral
Hungary		Chinoin Pharmaceuticals and Chemical Works Co Ltd 1045 H-Budapest, To utca 1-5 Tél: 0036 1 505 0000 Fax: 0036 1 505 0005	Doxazosin Winthrop 4mg Tablettes	4 mg	Prolonged release tablets	Oral
Poland		Winthrop Medicaments 1-13 Bd Romain Rolland F-75014, Paris Tél: 0033 (0) 1 57 63 33 33 Fax: 0033 (0) 1 57 63 33 30	DOXAWIN XL	4 mg	Prolonged release tablets	Oral
Slovakia		Winthrop Médicaments 1-13 Bd Romain Rolland F-75014 Paris Tél: 0033 (0) 1 57 63 33 33 Fax: 0033 (0) 1 57 63 33 30	Doxazosin Winthrop XL 4 mg	4 mg	Prolonged release tablets	Oral
Spain		Winthrop Pharmaceuticals UK Ltd 1 Onslow Street Guildford Surrey GU1 4YS United Kingdom Tél: 00 44 (0) 1483 55 48 31 Fax: 00 44 (0) 1483 55 48 31	Doxazosina WINTHROP 4 mg comprimidos de liberación prolongada EFG	4 mg	Prolonged release tablets	Oral
United Kingdom		Winthrop Pharmaceuticals UK Ltd 1 Onslow Street Guildford Surrey GU1 4YS United Kingdom	Slocinx XL 4mg Tablets	4 mg	Prolonged release tablets	Oral

## ANNEX III

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),  
ROUTE(S) OF ADMINISTRATION, APPLICANT(S)/ MARKETING AUTHORISATION HOLDER(S) IN THE  
MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Czech Republic		Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Tél: 0049 731 40202 Fax: 0049 731 4027330	Lansoprazol-ratiopharm 4 mg Hartkapseln	4 mg	Prolonged release tablets	Oral
Denmark	Pharmcom Oy Keijumaki 6B 30 FIN-02130 Espoo Tél: 00358 407 075670 Fax: 00358 94524872		Cardoreg 4 mg depotta- bletter	4 mg	Prolonged release tablets	Oral
Hungary		Ratiopharm Hungaria Kft. Uzoki utca 36/a H-1145 Budapest Tél: 0036 1 2732730 Fax: 0036 1 2732731	Doxazosin-ratiopharm retard 4 mg tableta	4 mg	Prolonged release tablets	Oral
Poland		Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Tél: 0049 731 40202 Fax: 0049 731 4027330	Doxazosin-ratiopharm retard PR4	4 mg	Prolonged release tablets	Oral
Slovakia		Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Tél: 0049 731 40202 Fax: 0049 731 4027330	Doxazosin-ratiopharm retard 4 mg	4 mg	Prolonged release tablets	Oral
United Kingdom		Ratiopharm GmbH Graf-Arco-Strasse 3 D-89079 Ulm Tél: 0049 731 40202 Fax: 0049 731 4027330	DoxaCard XL 4 mg prolonged release tablets	4 mg	Prolonged release tablets	Oral

## ANNEX IV

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),  
ROUTE(S) OF ADMINISTRATION, APPLICANT(S)/MARKETING AUTHORISATION HOLDER(S) IN THE  
MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Generics [UK] Ltd. Station Close Potters Bar Herts EN6 1TL. United Kingdom Tél: 00 44 1707 853000 Fax: 00 44 1707 650734		Doxagamma	4mg	Prolonged-release tablet	oral
United Kingdom		Generics [UK] Ltd., Station Close, Potters Bar, Herts,EN6 1TL. United Kingdom Tél: 00 44 1707 853000 Fax: 00 44 1707 650734	Doxzogen XL 4mg Tablets	4mg	Prolonged-release tablet	oral

## ANNEX V

**LIST OF THE NAMES, PHARMACEUTICAL FORM(S), STRENGTH(S) OF THE MEDICINAL PRODUCT(S),  
ROUTE(S) OF ADMINISTRATION, APPLICANT(S) MARKETING AUTHORISATION HOLDER(S) IN THE  
MEMBER STATES**

Member State	Marketing Authorisation Holder	Applicant	Name	Strength	Pharmaceutical Form	Route of administration
Denmark	Arrow Generics UK Ltd Unit 2 Eastman Way Stevenage Hertfordshire, SG1 4SZ United Kingdom Tél.: 00 44 207 612 7612 Fax: 00 44 207 612 7620		Doxazosin 'Arrow', 4mg depottabletter	4 mg	Prolonged release tablets	Oral
Portugal		Arrowblue Produtos Farmacêuticos S.A. Torre Fernão Magalhães 10º Esq., Av. D. João II — P- Lisbonne Tél.: 00 351 21 896 51 05 Fax: 00 351 21896 51 05	Doxazosin Arrow 4mg comprimido de libertação prolongada	4 mg	Prolonged release tablets	Oral
Slovenia		Arrow Generics UK Ltd Unit 2 Eastman Way Stevenage Hertfordshire, SG1 4SZ United Kingdom Tél.: 00 44 207 612 7612 Fax: 00 44 207 612 7620	Doksazosin Arrow 4mg tablete s podal- jšanim sproščanjem	4 mg	Prolonged release tablets	Oral
United Kingdom		Arrow Generics UK Ltd Unit 2 Eastman Way Stevenage Hertfordshire, SG1 4SZ United Kingdom Tél.: 00 44 207 612 7612 Fax: 00 44 207 612 7620	Cardozin XL 4mg	4 mg	Prolonged release tablets	Oral

## ANNEX VI

**LIST OF NAMES, PHARMACEUTICAL FORM OF THE MEDICINAL PRODUCTS, ANIMAL SPECIES,  
ROUTE OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER  
STATES**

Member State	Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Animal species	Frequency	Recommended dose	Withdrawal period (meat and milk)
Belgium	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Czech Republic	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC intramam susp. Ad us. Vet	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Germany	Intervet Deutschland GmbH Feldstr. 1a D-85716 Unterschleis- sheim	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Estonia	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Greece	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Spain	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
France	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC suspen- sion intramammaire	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Ireland	Intervet Ireland Magna Drive Magna Business Park Citywest Road IE-Dublin 24	Cephaguard DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Italy	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days

Member State	Marketing Authorisation Holder	Product invented name	Pharmaceutical form	Animal species	Frequency	Recommended dose	Withdrawal period (meat and milk)
Cyprus	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Latvia	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Lithuania	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Luxembourg	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Austria	Intervet Gesmbh Siemens- strasse 107 A -1210 Vienne	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Poland	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Portugal	Intervet Portugal, Lda. Estrada Nacional 249 PT-2725-397 Mem Martins	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Slovenia	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
Slovakia	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days
United Kingdom	Intervet International B.V. Wim de Körverstraat 35 NL -5831 AN Boxmeer	Cobactan DC	Intramammary ointment	Dairy cows	Single dose	150 mg cefquinome	Meat and offal: 2 days Milk: 49 days