



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2012
EMA/764460/2012
Patient Health Protection

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for diacerein containing medicinal products

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1349

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Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	TRB Chemedica (Austria) GmbH IZ NOE- Sued, Straße 7, Obj. 58D/1/2.OG 2355 Wiener Neudorf Austria	ARTROLYT 50 mg Kapseln	50 mg	capsule, hard	oral use
Austria	TRB Chemedica (Austria) GmbH IZ NOE- Sued, Straße 7, Obj. 58D/1/2.OG 2355 Wiener Neudorf Austria	VERBORIL 50 mg Kapseln	50 mg	capsule, hard	oral use
Czech Republic	TRB Chemedica (Austria) GmbH IZ NOE- Sued, Straße 7, Obj. 58D/1/2.OG 2355 Wiener Neudorf Austria	ARTRODAR	50 mg	capsule, hard	oral use
France	NEGMA 10, rue Paul Dautier 78140 Vélizy Villacoublay FRANCE	ART 50 mg, gélule	50 mg	capsule, hard	oral use
France	ACTAVIS GROUP (ISLANDE) Reykjavíkurvegur 76-78 220 Hafnarfjörður ISLANDE	DIACEREINE ACTAVIS 50 mg, gélule	50 mg	capsule, hard	oral use
France	ARROW GENERIQUES 26, avenue Tony Garnier 69007 Lyon FRANCE	DIACEREINE ARROW 50 mg, gélule	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 Colombes FRANCE	DIACEREINE BIOGARAN 50 mg, gélule	50 mg	capsule, hard	oral use
France	CRISTERS 22 quai Gallieni 92150 Suresnes FRANCE	DIACEREINE CRISTERS 50 mg, gélule	50 mg	capsule, hard	oral use
France	EG LABO - LABORATOIRES EUROGENERICS "Le Quintet" - bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex FRANCE	DIACEREINE EVOLUGEN 50 mg, gélule	50 mg	capsule, hard	oral use
France	EVOLUPHARM rue Irène Caron Zone Industrielle d'Auneuil 60390 Auneuil FRANCE	DIACEREINE EVOLUGEN 50 mg, gélule	50 mg	capsule, hard	oral use
France	SUBSTIPHARM DEVELOPPEMENT 8, rue Bellini 75116 Paris FRANCE	DIACEREINE GENODEX 50 mg, gélule	50 mg	capsule, hard	oral use
France	MAZAL PHARMACEUTIQUE 11, rue Rontgen BP 1309 29103 Quimper FRANCE	DIACEREINE MAZAL 50 mg, gélule	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest FRANCE	DIACEREINE MYLAN 50 mg, gélule	50 mg	capsule, hard	oral use
France	NEGMA 10, rue Paul Dautier 78140 Vélizy Villacoublay FRANCE	DIACEREINE NEGMA 50 mg, gélule	50 mg	capsule, hard	oral use
France	LABORATOIRES PHARMA 2000 10 rue Paul Dautier 78140 Vélizy Villacoublay FRANCE	DIACEREINE PHARMA 2000 50 mg, gélule	50 mg	capsule, hard	oral use
France	QUALIMED (LYON) 117, allée des Parcs 69800 Saint-Priest FRANCE	DIACEREINE QUALIMED 50 mg, gélule	50 mg	capsule, hard	oral use
France	RANBAXY PHARMACIE GENERIQUES 11-15 Quai Dion Bouton 92800 Puteaux FRANCE	DIACEREINE RANBAXY 50 mg, gélule	50 mg	capsule, hard	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex FRANCE	DIACEREINE RATIOPHARM 50 mg, gélule	50 mg	capsule, hard	oral use
France	BIOGARAN 15, boulevard Charles de Gaulle 92700 C olombes FRANCE	DIACEREINE REF 50 mg, gélule	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	SANDOZ 49, avenue Georges Pompidou 92300 Levallois-Perret FRANCE	DIACEREINE SANDOZ 50 mg, gélule	50 mg	capsule, hard	oral use
France	SUBSTIPHARM DEVELOPPEMENT 8, rue Bellini 75116 Paris FRANCE	DIACEREINE SUBSTILAB 50 mg, gélule	50 mg	capsule, hard	oral use
France	SUBSTIPHARM DEVELOPPEMENT 8, rue Bellini 75116 Paris FRANCE	DIACEREINE SUBSTIPHARM 50 mg, gélule	50 mg	capsule, hard	oral use
France	TEVA SANTE 110, Esplanade du Général de Gaulle 92931 Paris La Défense Cedex FRANCE	DIACEREINE TEVA 50 mg, gélule	50 mg	capsule, hard	oral use
France	SANOFI AVENTIS FRANCE 1-13, boulevard Romain Rolland 75014 Paris FRANCE	DIACEREINE ZENTIVA 50 mg, gélule	50 mg	capsule, hard	oral use
France	ZYDUS FRANCE 25, rue des Peupliers ZAC Les Hautes Pâtures - Parc d'Activités des Peupliers 92000 Nanterre FRANCE	DIACEREINE ZYDUS 50 mg, gélule	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	MAZAL PHARMACEUTIQUE 11, rue Rontgen BP 1309 29103 Quimper FRANCE	MAZART 50 mg, gélule	50 mg	capsule, hard	oral use
France	NIVERPHARM 10 rue Paul Dautier 78140 Vélizy Villacoublay FRANCE	ZONDAR 50 mg, gélule	50 mg	capsule, hard	oral use
Greece	ANGELINI PHARMA HELLAS Nea Kifissia 14564, Athens Greece	VERBORIL	50 mg	capsule, hard	oral use
Greece	Genepharm a.e. 18th km Marathonos Avenue, Pallini, Attikis, 15351 Greece	ARTHROREIN	50 mg	capsule, hard	oral use
Greece	VOCATE Pharmaceuticals S.A., Gounari 150, Glyfada 16674, Athens Greece	ARTHROFAR	50 mg	capsule, hard	oral use
Greece	Rafarm Aebe Korinthou 12, Neo Psychiko, 15451 Greece	IDEALITE	50 mg	capsule, hard	oral use
Greece	HELP ABEE Valaoritou 10, Metamorfosi, Attikis, 14452 Greece	INFLABION	50 mg	capsule, hard	oral use

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Greece	BROS EPE Avgis & Gallinis 15, n. Kifissia, 14564 Greece	REUMANISAL	50 mg	capsule, hard	oral use
Greece	FARMEDIA A.E. Athinias 22 & Apollonos Gerakas, Attikis, 15344 Greece	OSTIREIN	50 mg	capsule, hard	oral use
Greece	GENEPHARM A.E. 18th km Marathonos Avenue, Pallini, Attikis, 15351 Greece	MYOBLOC	50 mg	capsule, hard	oral use
Greece	PHARMACEUTICAL INDUSTRY Proel Epam. G. Koronis Dilou 9, Peristeri, Attikis, 12134 Greece	DIACEREIN /PROEL	50 mg	capsule, hard	oral use
Greece	NORMA HELLAS A.E. Menandrou 54, Athens, 10431 Greece	DIACEREIN /NORMA	50 mg	capsule, hard	oral use
Greece	S.M. Pharmaceutical Products Ltd, Agiou Orous 43-45, Piraeus 18545 Greece	DESEREIN	50 mg	capsule, hard	oral use
Greece	PROTON PHARMA Anonymous Pharmaceutical Company, Achaias 4 and Trizinias, Nea Kifissia 14564 Greece	DIACERIL	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Italy	ABIOGEN PHARMA S.p.A. Via Meucci 36 56014 Ospedaletto – Pisa Italy	FISIODAR	50 mg	capsule, hard	oral use
Portugal	Neo-Farmacêutica, S.A. Av. D. João II, Lote 1.02.2.1 D-2º 1990-090 Lisboa Portugal	Artrolyt	50 mg	capsule, hard	oral use
Slovak Republic	TRB CHEMEDICA (Austria) GmbH, IZ NOE-Sued, Strasse 7, Obj.58D/1/2.OG, 2355 Wiener Neudorf, Austria	ARTRODAR	50 mg	capsule, hard	oral use
Spain	ROTTAPHARM S.L. Avda. Diagonal, 67-69 08019 Barcelona Spain	GLIZOLAN 50 mg cápsulas	50 mg	capsule, hard	oral use
Spain	NEGMA-LERADS Immeuble Strasbourg Avenue de L'Europe Toussus-le-Noble Magny-les Hameaux Cedex F-78771 France	ARTRIZAN 50 mg cápsulas	50 mg	capsule, hard	oral use
Spain	LACER S.A. Sardenya, 350 08025 Barcelona Spain	GALAXDAR 50 mg cápsulas	50 mg	capsule, hard	oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Spain	LABORATORIOS NORMON S.A. Ronda de Valdecarrizo, 6 28760 Tres Cantos (Madrid) Spain	DIACEREINA NORMON 50 mg cápsulas duras EFG	50 mg	capsule, hard	oral use
Spain	IBERMEDGEN S.A. Ronda de Valdecarrizo, 6 28760 Tres Cantos (Madrid) Spain	DIACEREINA PANLUETOL 50 mg cápsulas duras EFG	50 mg	capsule, hard	oral use
Spain	MG PHARMA 8, Rue Bellini 75116 Paris France	REINART 50 mg cápsulas duras EFG	50 mg	capsule, hard	oral use