



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 January 2016
EMA/1461/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: paracetamol (IV formulation)

Procedure no.: PSUSA/00002311/201505



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Algocit		20113/13/21-05-2014	DEMO S.A.	Greece
Acamol	DE-H-1908-001-DC	4750/2012/01-08	Teva Pharmaceuticals S.R.L.	Romania
Apotel		09/H/0171/001	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Portugal
Apotel		43355/12/20.02.2013	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Apotel Max		101303/12.12.2014	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Apotel		S00546	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Cyprus
Apotel	NL/H/2857/001	54977	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Denmark
Apotel	NL/H/2857/001	RVG 113095	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Netherlands
Apotel Max		21966	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Cyprus
Exopon		70077/14/03.02.2015	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Greece
Exopon	NL/H/2857/001/DC	043471010 \$ 043471022 \$ 043471034 \$ 043471046	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Italy
Exopon	NL/H/2857/001	51968	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Sweden
Exopon	NL/H/2857/001	93352.00.00	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Germany
Helporal Solution for Infusion 10mg/ml		42623/12/18-02-2013	Medicus S.A.	Greece
Lekadol		UP/I-530-09/12-01/358	Sandoz D.O.O.	Croatia

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Paracetamol	DE-H-1908-001-DC	PA 749/145/1	Teva Pharma B.V. Computerweg 10	Ireland
Paracetamol B Braun	DE/H/3084/001/DC	NL 40 875	B. Braun Melsungen Ag Art 57	France
Paracetamol B. Braun	DE/H/3084/001	07/0159/12-S	B. Braun Melsungen Ag Art 57	Slovakia
Paracetamol B. Braun	DE/H/3084/001	1-31280	B. Braun Melsungen Ag Art 57	Austria
Paracetamol B. Braun	DE/H/3084/001	12-0052	B. Braun Melsungen Ag Art 57	Latvia
Paracetamol B. Braun	DE/H/3084/001	20317	B. Braun Melsungen Ag Art 57	Poland
Paracetamol B. Braun	DE/H/3084/001	45748	B. Braun Melsungen Ag Art 57	Sweden
Paracetamol B. Braun	DE/H/3084/001	5442967 \$ 5442975	B. Braun Melsungen Ag Art 57	Portugal
Paracetamol B. Braun	DE/H/3084/001	777112	B. Braun Melsungen Ag Art 57	Estonia
Paracetamol B. Braun	DE/H/3084/001	83987.00.00	B. Braun Melsungen Ag Art 57	Germany
Paracetamol B. Braun	DE/H/3084/001	PL 03551/0128	B. Braun Melsungen Ag Art 57	United Kingdom
Paracetamol B. Braun	DE/H/3084/001	RVG 109193	B. Braun Melsungen Ag Art 57	Netherlands
Paracetamol B. Braun	DE/H/3084/001/DC	07/221/12-C	B. Braun Melsungen Ag	Czech Republic

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Paracetamol B. Braun	DE/H/3084/001/DC	11-8174	B. Braun Melsungen Ag Art 57	Norway
Paracetamol B. Braun	DE/H/3084/001/DC	2012090064	B. Braun Melsungen Ag Art 57	Luxembourg
Paracetamol B. Braun	DE/H/3084/001/DC	29564	B. Braun Melsungen Ag Art 57	Finland
Paracetamol B. Braun	DE/H/3084/001/DC	4714/2012/01-02	B. Braun Melsungen Ag Art 57	Romania
Paracetamol B. Braun	DE/H/3084/001/DC	48517	B. Braun Melsungen Ag Art 57	Denmark
Paracetamol B. Braun	DE/H/3084/001/DC	5363-I-1511/12,5363-I-1510/12	B. Braun Medical, S.A. Art 57	Slovenia
Paracetamol B. Braun	DE/H/3084/001/DC	75594	B. Braun Melsungen Ag Art 57	Spain
Paracetamol B. Braun	DE/H/3084/001/DC	BE416175 \$ BE416184 \$ BE464417	B. Braun Melsungen Ag Art 57	Belgium
Paracetamol B. Braun	DE/H/3084/001/DC	LT/1/12/2954/001 \$ LT/1/12/2954/002 \$ LT/1/12/2954/003	B. Braun Melsungen Ag Art 57	Lithuania
Paracetamol B. Braun	DE/H/3084/001/DC	PA 0736/035/001	B. Braun Melsungen Ag Art 57	Ireland
Paracetamol B. Braun		UP/I-530-09/13-01/02	B. Braun Adria D.O.O.	Croatia
Paracetamol Color		5368758	Color Pharma, Lda.	Portugal
Paracetamol Combino	PT/H/1902/001/DC	5274006, 5274014, 5335179, 5335203, 5335211	Combino Pharm S.L	Portugal

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Paracetamol Combino Pharm	DE/H/1902/001/DC	72112	Accord Healthcare S.L.U.	Spain
Paracetamol Farmoz		5377460 \$ 5377478 \$ 5377502 \$ 5377510	Farmoz - Sociedade Técnico Medicinal, S.A.	Portugal
Paracetamol Fresenius Kabi	DE/H/2511/001	09-6966	Fresenius Kabi Norge As	Norway
Paracetamol Fresenius Kabi	DE/H/2511/001	27825	Fresenius Kabi Ab	Finland
Paracetamol Fresenius Kabi	DE/H/2511/001	42920	Fresenius Kabi Ab	Sweden
Paracetamol Fresenius Kabi	DE/H/2511/001	45499	Fresenius Kabi Ab	Denmark
Paracetamol Fresenius Kabi	DE/H/2511/001	PA 566/57/1 \$ PA 566/57/2	Fresenius Kabi Limited	Ireland
Paracetamol Fresenius Kabi	DE/H/2511/001	PL 08828/0226	Fresenius Kabi Limited	United Kingdom
Paracetamol Fresenius Kabi	DE/H/2511/001	RVG 105747	Fresenius Kabi Nederland B.V.	Netherlands
Paracetamol Fresenius Kabi	DE/H/2511/001 \$ DE/H/2511/001/DC	BE379775 \$ BE379784 \$ BE442181 \$ BE442197	Fresenius Kabi Nv/Sa	Belgium
Paracetamol G.E.S.		68.474	G.E.S. Genéricos Españoles Laboratorio, S.A.	Spain
Paracetamol Generis		5423520 \$ 5423538	Generis Farmacêutica, S.A.	Portugal
Paracetamol Kabi		UP/I-530-09/12-01/271	Fresenius Kabi D.O.O.	Croatia
Paracetamol Kabi	DE/H/2511/001	0452/11010162	Fresenius Kabi Deutschland Gmbh	Luxembourg

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Paracetamol Kabi	DE/H/2511/001	07/0728/10-S	Fresenius Kabi S.R.O	Slovakia
Paracetamol Kabi	DE/H/2511/001	07/967/10-C	Fresenius Kabi S.R.O	Czech Republic
Paracetamol Kabi	DE/H/2511/001	1-30043	Fresenius Kabi Austria Gmbh	Austria
Paracetamol Kabi	DE/H/2511/001	10-0611	Fresenius Kabi Polska Sp. Z O.O.	Latvia
Paracetamol Kabi	DE/H/2511/001	18152	Fresenius Kabi Polska Sp. Z O.O.	Poland
Paracetamol Kabi	DE/H/2511/001	9451/13/3-1-2014	Fresenius Kabi Hellas A.E.	Greece
Paracetamol Kabi	DE/H/2511/001	5338645 \$ 5338652 \$ 5338660 \$ 5338678 \$ 5338702 \$ 5338710 \$ 5338728 \$ 5338736 \$ 5584255 \$ 5584263 \$ 5584271 \$ 5584305 \$ 5584313 \$ 5584321	Fresenius Kabi Pharma Portugal Lda.	Portugal
Paracetamol Kabi	DE/H/2511/001	5363-I-1521/13 \$ 5363-I-1522/13 \$ 5363-I-1720/11 \$ 5363-I-1721/11 \$ 5363-I-1722/11 \$ 5363-I-1723/11 \$ 5363-I-1724/11 \$ 5363-I-1725/11 \$ 5363-I-1726/11 \$ 5363-I-1727/11	Fresenius Kabi Deutschland Gmbh	Slovenia
Paracetamol Kabi	DE/H/2511/001	715010	Fresenius Kabi Polska Sp. Z O.O.	Estonia
Paracetamol Kabi	DE/H/2511/001	74477	Fresenius Kabi España S.A.U.	Spain
Paracetamol Kabi	DE/H/2511/001	78789.00.00	Fresenius Kabi Deutschland Gmbh	Germany
Paracetamol Kabi	DE/H/2511/001 \$ DE/H/2511/001/DC	LT/1/10/2268/001 \$ LT/1/10/2268/002 \$ LT/1/10/2268/003 \$ LT/1/10/2268/004 \$ LT/1/10/2268/005 \$ LT/1/10/2268/006 \$ LT/1/10/2268/007 \$ LT/1/10/2268/008 \$ LT/1/10/2268/009 \$ LT/1/10/2268/010 \$ LT/1/10/2268/011 \$ LT/1/10/2268/012 \$ LT/1/10/2268/013 \$ LT/1/10/2268/014	Fresenius Kabi Polska Sp. Z O.O.	Lithuania

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Paracetamol Kabi	DE/H/2511/001 \$ DE/H/2511/001/DC	OGYI-T-21800/01 \$ OGYI-T-21800/02 \$ OGYI-T-21800/03 \$ OGYI-T-21800/04 \$ OGYI-T-21800/05 \$ OGYI-T-21800/06 \$ OGYI-T-21800/07 \$ OGYI-T-21800/08 \$ OGYI-T-21800/09 \$ OGYI-T-21800/10 \$ OGYI-T-21800/11 \$ OGYI-T-21800/12 \$ OGYI-T-21800/13 \$ OGYI-T-21800/14	Fresenius Kabi Hungary Kft.	Hungary
Paracetamol Kabi	DE/H/2511/001/DC	3225/2011/01 \$ 3225/2011/02 \$ 3225/2011/03 \$ 3225/2011/04 \$ 3225/2011/05 \$ 3225/2011/06 \$ 3225/2011/07 \$ 3225/2011/08 \$ 3225/2011/09 \$ 3225/2011/10 \$ 3225/2011/11 \$ 3225/2011/12 \$ 3225/2011/13 \$ 3225/2011/14	Fresenius Kabi Romania S.R.L.	Romania
Paracetamol Kern Pharma	PT/H/1003/001/DC	78690	Kern Pharma, S.L.	Spain
Paracetamol Maco Pharma	FR/H/0472/001	PA 931/10/01	Maco Pharma (Uk) Ltd	Ireland
Paracetamol Maco Pharma	FR/H/0472/001	PL12580/0021	Maco Pharma (Uk) Ltd	United Kingdom
Paracetamol Macopharma	FR/H/0472/001	ENR 2182489	Maco Pharma International Gmbh	Germany
Paracetamol Macopharma	FR/H/0472/001	BE 393994 \$ BE 394003 \$ BE 394012 \$ BE 394021 \$ BE 458773	Maco Pharma Benelux	Belgium
Paracetamol Macopharma	FR/H/0472/001	BE 393994 \$ BE 394003 \$ BE 394012 \$ BE 394021 \$ BE 458773	Maco Pharma Benelux	Belgium

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Paracetamol Macopharma		NL 37 826	Maco Pharma	France
Paracetamol Macopharma	FR/H/0472/001/MR	1211/11030030	Maco Pharma	Luxembourg
Paracetamol Morningside Healthcare Ltd		PL 20117/0204	Morningside Healthcare Ltd	United Kingdom
Paracetamol Noridem	PT/H/1003/001/DC	5607452 \$ 5607460 \$ 5607478 \$ 5607502 \$ 5607510 \$ 5607528 \$ 5607536 \$ 5607544	Noridem Enterprises Ltd	Portugal
Paracetamol Noridem	PT/H/1003/001/DC	89627.00.00	Noridem Enterprises Ltd	Germany
Paracetamol Noridem Enterprises Ltd.	PT/H/1003/001/DC	PL 24598/0028	Noridem Enterprises Ltd	United Kingdom
Paracetamol Normon		71530	Laboratorios Normon, S.A.	Spain
Paracetamol Panpharma	FR/H/0355/001	08-5909	Panmedica	Norway
Paracetamol Panpharma	FR/H/0355/001	10-0627	Panmedica	Latvia
Paracetamol Panpharma	FR/H/0355/001	18132	Panmedica	Poland
Paracetamol Panpharma	FR/H/0355/001	26934	Panmedica	Sweden
Paracetamol Panpharma	FR/H/0355/001	28579	Panmedica	Finland

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Paracetamol Panpharma	FR/H/0355/001	3337/2011/01 \$ 3337/2011/02 \$ 3337/2011/03 \$ 3337/2011/04 \$ 3337/2011/05 \$ 3337/2011/06	Panmedica	Romania
Paracetamol Panpharma	FR/H/0355/001	NL 34277	Panmedica	France
Paracetamol Panpharma	FR/H/0355/001	34009 571 860 1 2 \$ 34009 571 861 8 0 \$ 34009 571 862 4 1 \$ 34009 571 863 0 2 \$ 34009 572 996 4 4 \$ 34009 572 997 0 5 \$ 34009 585 640 9 3 \$ 34009 585 641 5 4 \$ 34009 585 642 1 5 \$ 34009 585 643 8 3 \$ 34009 585 644 4 4 \$ 34009 585 645 0 5 \$ 34009 585 646 7 3 \$ 34009 585 647 3 4 \$ 34009 585 649 6 3	Panmedica	France
Paracetamol Panpharma	FR/H/0355/001	43307	Panmedica	Denmark
Paracetamol Panpharma	FR/H/0355/001	LT/1/10/2343/001 \$ LT/1/10/2343/002 \$ LT/1/10/2343/003 \$ LT/1/10/2343/004 \$ LT/1/10/2343/005 \$ LT/1/10/2343/006 \$ LT/1/10/2343/007 \$ LT/1/10/2343/008 \$ LT/1/10/2343/009 \$ LT/1/10/2343/010 \$ LT/1/10/2343/011 \$ LT/1/10/2343/012	Panmedica	Lithuania

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Paracetamol Panpharma	FR/H/0355/001	OGYI-T-21749/01 \$ OGYI-T-21749/02 \$ OGYI-T-21749/03 \$ OGYI-T-21749/04 \$ OGYI-T-21749/05 \$ OGYI-T-21749/06 \$ OGYI-T-21749/07 \$ OGYI-T-21749/08 \$ OGYI-T-21749/09 \$ OGYI-T-21749/10 \$ OGYI-T-21749/11 \$ OGYI-T-21749/12 \$ OGYI-T-21749/13 \$ OGYI-T-21749/14 \$ OGYI-T-21749/15	Panmedica	Hungary
Paracetamol Pentafarma	PT/H/0554/001	5455142 \$ 5455159 \$ 5455167 \$ 5461629	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Portugal
Paracetamol Pharmaswiss		UP/I-530-09/12-01/168	Pharmaswiss česká Republika S.R.O.	Croatia
Paracetamol Polpharma	DE/H/3247/001	20959	Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna	Poland
Paracetamol Rotexmedica	FR/H/0355/001	73831.00.00	Panmedica	Germany
Paracetamol Sandoz	DE/H/3248/001	BE426151	Sandoz N.V.	Belgium
Paracetamol Sandoz Ltd	DE/H/3248/001	PL 04416/1388	Sandoz Ltd	United Kingdom
Paracetamol Tecnigen	PT/H/554/001/DC	689267, 605847, 689268, 605848	Tecnimede España Ind. Fca., S.A.	Spain
Paracetamol Teva	DE-H-1908-001-DC	47882	Teva Denmark A/S	Denmark
Paracetamol Teva	DE-H-1908-001-DC	51688/1-7-2013	Teva Pharma B.V. Computerweg 10	Greece
Paracetamol Teva	DE-H-3247-01-DC	2014120418	Teva Pharma Belgium N.V.	Luxembourg
Paracetamol Teva	DE-H-3247-01-DC	BE451244 \$ BE474417	Teva Pharma Belgium N.V.	Belgium

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Paracetamol Teva 10mg/MI	DE-H-1908-001-DC	20120212	Teva Pharmaceuticals Bulgaria Eood	Bulgaria
Paracetamol Teva,	DE-H-1908-001-DC	RVG 108752	Teva Nederland B.V.	Netherlands
Paracetamol Uni-Pharma	NL/H/2857/001	5649728 \$ 5649736 \$ 5649744 \$ 5649751	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Portugal
Paracetamol Uni-Pharma	NL/H/2857/001	PL 20989/0010	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	United Kingdom
Paracetamol-Ratiopharm	DE-H-1908-001-DC	74700.00.00	Ratiopharm Gmbh	Germany
Paracetamolo Galenica Senese	DE/H/2052/1/DC	041160019 \$ 041160021 \$ 041160033 \$ 041160045 \$ 041160058	Industria Farmaceutica Galenica Senese S.R.L..	Italy
Paracetamolo Hospira 10 mg/ml soluzione per infusione		041160019 \$ 041160021 \$ 041160033 \$ 041160045 \$ 041160058	Hospira	Italy
Paracetamolo B. Braun	DE/H/3084/001 \$ DE/H/3084/001/DC	040798011 \$ 040798023 \$ 040798035	B. Braun Melsungen Ag Art 57	Italy
Paracetamolo Kabi	DE/H/2511/001	040381016 \$ 040381028 \$ 040381030 \$ 040381042 \$ 040381055 \$ 040381067 \$ 040381079 \$ 040381081 \$ 040381093 \$ 040381105 \$ 040381117 \$ 040381129 \$ 040381131 \$ 040381143	Fresenius Kabi Italia S.R.L.	Italy
Parafusiv		5423553	Pharma Bavaria Internacional Portugal Unip. Lda	Portugal

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Parafusiv		5423546	Pharma Bavaria Internacional Portugal Unip. Lda	Portugal
Perfalgan	FR/H/0197/001	035475019 \$ 035475033	Bristol-Myers Squibb S.R.L.	Italy
Perfalgan	FR/H/0197/001	035475021	Bristol-Myers Squibb S.R.L.	Italy
Perfalgan	FR/H/0197/001	07/306/03-C	Bristol-Myers Squibb Spol. S R.O.	Czech Republic
Perfalgan	FR/H/0197/001	1-24349	Bristol-Myers Squibb Gesmbh	Austria
Perfalgan	FR/H/0197/001	32926	Bristol-Myers Squibb Gesmbh	Denmark
Perfalgan	FR/H/0197/001	16778	Bristol-Myers Squibb AB	Finland
Perfalgan	FR/H/0197/001	05-0223	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Latvia
Perfalgan	FR/H/0197/001	34009 563 624 0 0	Bristol-Myers Squibb	France
Perfalgan	FR/H/0197/001	11887	Bristol-Myers Squibb Polska Sp. z o.o.	Poland
Perfalgan	FR/H/0197/001	34009 563 059 1 9	Bristol-Myers Squibb	France
Perfalgan	FR/H/0197/001	3856283 \$ 3856481 \$ 4989083 \$ 5013081 \$ 5245022	Bristol-Myers Squibb Farmacêutica Portuguesa, Sa	Portugal
Perfalgan	FR/H/0197/001	469605	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Estonia
Perfalgan	FR/H/0197/001	52600.00.00	Bristol-Myers Squibb Gmbh & Co. Kgaa	Germany
Perfalgan	FR/H/0197/001	64.535	Bristol-Myers Squibb	Spain
Perfalgan	FR/H/0197/001	LT/1/05/0219/001 \$ LT/1/05/0219/002	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Lithuania
Perfalgan	FR/H/0197/001	PA 2/69/1	Bristol-Myers Squibb Pharmaceuticals Limited	Ireland

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Perfalgan	FR/H/0197/001	PL 11184/0094	Bristol-Myers Squibb Pharmaceuticals Limited	United Kingdom
Perfalgan	FR/H/197/01	IS/1/01/049/01	Bristol-Myers Squibb Ab	Iceland
Supofen		5431606	Laboratórios Basi – Indústria Farmacêutica, S.A.	Portugal
Tachipirina	National	012745232 \$ 012745244 \$ 012745257 \$ 012745269	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Italy
парацетамол б. браун	DE/H/3084/001	20120293	B. Braun Melsungen Ag Art 57	Bulgaria
парацетамол биофарм		20140040	Biopharm Engineering	Bulgaria
парацетамол каби	DE/H/2511/001	20120453	Fresenius Kabi Bulgaria Eood	Bulgaria
Paracetamol Panpharma	FR/H/0355/001	11875	Panmedica	Bulgaria
Paracetamol Renaudin		34009 578 843 5 2	Laboratoire Renaudin	France