



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2023
EMA/PRAC/222132/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): lysine acetylsalicylate

Procedure No. PSUSA/00001921/202209



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
ASPEGIC 100 mg poeder voor drank	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poeder voor drank	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poeder voor drank	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poudre pour solution buvable	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poudre pour solution buvable	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poudre pour solution buvable	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg poudre pour solution buvable	not available	0285481	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 100 mg poudre pour solution buvable	not available	0164986	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 100 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 100 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120617	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE

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
ASPEGIC 100, 180 mg de acetilsalicilato de lisina pó para solução oral	not available	8520809	OPELLA HEALTHCARE PORTUGAL UNIPessoal LDA.	PT
ASPEGIC 1000 mg poeder voor drank	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poeder voor drank	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poeder voor drank	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poeder voor drank	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poudre pour solution buvable	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poudre pour solution buvable	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poudre pour solution buvable	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poudre pour solution buvable	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg poudre pour solution buvable	not available	0165014	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 1000 mg poudre pour solution buvable	not available	0008351	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 1000 mg poudre pour solution	not available	0165001	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM	LU

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
buvable			SANOFI BELGIUM)	
ASPEGIC 1000 mg poudre pour solution buvable	not available	0285771	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 1000 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 1000 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE120766	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
Aspegic 1000, 1800 mg de acetilsalicilato de lisina pó para solução oral	not available	8520825	OPELLA HEALTHCARE PORTUGAL UNIPESAOAL LDA.	PT
ASPEGIC 250 mg poeder voor drank	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 250 mg poeder voor drank	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 250 mg poudre pour solution buvable	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 250 mg poudre pour solution buvable	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 250 mg poudre pour solution buvable	not available	0008379	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 250 mg poudre	not available	0008365	OPELLA HEALTHCARE	LU

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
pour solution buvable			BELGIUM (HANDELSNAAM SANOFI BELGIUM)	
ASPEGIC 250 mg poudre pour solution buvable	not available	0285494	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 250 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 250 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE129762	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poeder voor drank	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poeder voor drank	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poeder voor drank	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poudre pour solution buvable	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poudre pour solution buvable	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poudre pour solution buvable	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg poudre pour solution buvable	not available	0008382	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 500 mg poudre pour solution buvable	not available	0285513	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
ASPEGIC 500 mg Pulver	not available	BE042287	OPELLA HEALTHCARE	BE

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
zur Herstellung einer Lösung zum Einnehmen			BELGIUM (HANDELSNAAM SANOFI BELGIUM)	
ASPEGIC 500 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE042287	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC 500 mg, poudre pour solution buvable en sachet-dose	not available	34009 347 361 5 5	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC 500 mg, poudre pour solution buvable en sachet-dose	not available	34009 312 268 9 5	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC 500 mg, poudre pour solution buvable en sachet-dose	not available	34009 316 963 3 9	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC 500 mg, poudre pour solution buvable en sachet-dose	not available	34009 347 360 9 4	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC 500 mg, poudre pour solution buvable en sachet-dose	not available	34009 334 387 0 8	OPELLA HEALTHCARE FRANCE SAS	FR
Aspegic 500, 900 mg de acetilsalicilato de lisina pó para solução oral	not available	8520817	OPELLA HEALTHCARE PORTUGAL UNIPessoal LDA.	PT
ASPEGIC ADULTES 1000 mg, poudre pour solution buvable en sachet-dose	not available	34009 318 980 2 3	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ADULTES 1000 mg, poudre pour solution buvable en sachet-dose	not available	34009 318 981 9 1	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ADULTES 1000 mg, poudre pour solution buvable en sachet-dose	not available	34009 357 067 2 0	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ADULTES 1000	not available	34009 311 982 5 2	OPELLA HEALTHCARE	FR

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
mg, poudre pour solution buvable en sachet-dose			FRANCE SAS	
ASPEGIC ADULTES 1000 mg, poudre pour solution buvable en sachet-dose	not available	34009 347 359 0 5	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ENFANTS 250 mg, poudre pour solution buvable en sachet-dose	not available	34009 327 035 5 5	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ENFANTS 250 mg, poudre pour solution buvable en sachet-dose	not available	34009 327 036 1 6	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ENFANTS 250 mg, poudre pour solution buvable en sachet-dose	not available	34009 554 666 6 6	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC ENFANTS 250 mg, poudre pour solution buvable en sachet-dose	not available	34009 327 037 8 4	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 1 g, poudre et solution pour préparation injectable	not available	34009 326 103 7 2	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 1 g, poudre et solution pour préparation injectable	not available	34009 334 388 7 6	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 1 g, poudre et solution pour préparation injectable	not available	34009 326 101 4 3	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 1 g, poudre et solution pour préparation injectable	not available	34009 326 102 0 4	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 1 g, poudre et solution pour préparation	not available	34009 556 102 2 9	OPELLA HEALTHCARE FRANCE SAS	FR

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
injectable				
ASPEGIC Injectable 500 mg poeder en oplosmiddel voor oplossing voor injectie	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC Injectable 500 mg poeder en oplosmiddel voor oplossing voor injectie	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC Injectable 500 mg poudre et solvant pour solution injectable	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC Injectable 500 mg poudre et solvant pour solution injectable	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
Aspegic Injectable 500 mg poudre et solvant pour solution injectable	not available	0008334	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	LU
Aspegic Injectable 500 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
Aspegic Injectable 500 mg Pulver und Lösungsmittel zur Herstellung einer Injektionslösung	not available	BE042201	OPELLA HEALTHCARE BELGIUM (HANDELSNAAM SANOFI BELGIUM)	BE
ASPEGIC INJECTABLE 500 mg/5 ml, poudre et solution pour usage parentéral	not available	34009 300 724 4 8	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 500 mg/5 ml, poudre et solution pour usage parentéral	not available	34009 556 101 6 8	OPELLA HEALTHCARE FRANCE SAS	FR

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
ASPEGIC INJECTABLE 500 mg/5 ml, poudre et solution pour usage parentéral	not available	34009 553 149 8 1	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTABLE 500 mg/5 ml, poudre et solution pour usage parentéral	not available	34009 300 725 0 9	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC INJECTIE 500, poeder en oplosmiddel voor oplossing voor injectie 500 mg/5 ml	not available	RVG 06305	OPELLA HEALTHCARE FRANCE SAS	NL
ASPEGIC NOURRISSONS 100 mg, poudre pour solution buvable en sachet-dose	not available	34009 334 386 4 7	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC NOURRISSONS 100 mg, poudre pour solution buvable en sachet-dose	not available	34009 318 936 3 9	OPELLA HEALTHCARE FRANCE SAS	FR
ASPEGIC NOURRISSONS 100 mg, poudre pour solution buvable en sachet-dose	not available	34009 318 938 6 8	OPELLA HEALTHCARE FRANCE SAS	FR
Aspirin® i.v. 500 mg, Pulver und Lösungsmittel zur Herstellung einer Injektions- oder Infusionslösung	not available	54243.00.00	BAYER VITAL GMBH	DE
CARDIRENE 100 mg Polvere per Soluzione Orale	not available	028717039	SANOFI S.R.L.	IT
CARDIRENE 160 mg Polvere per Soluzione Orale	not available	028717015	SANOFI S.R.L.	IT
CARDIRENE 300 mg	not available	028717027	SANOFI S.R.L.	IT

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
Polvere per Soluzione Orale				
CARDIRENE 75 mg Polvere per Soluzione Orale	not available	028717041	SANOFI S.R.L.	IT
Inyesprin	not available	51209	ARISTO PHARMA IBERIA, S.L.	ES
Kardegic 0,5 g prášek a rozpouštědlo pro injekční roztok	not available	16/078/02-C	SANOFI-AVENTIS SRO	CZ
Kardegic 0,5 g prášek a rozpouštědlo pro injekční roztok	not available	16/078/02-C	SANOFI-AVENTIS SRO	CZ
Kardegic 100 mg por belsőleges oldathoz	not available	OGYI-T-8755/02	SANOFI-AVENTIS ZRT	HU
KARDEGIC 160 mg, poudre pour solution buvable en sachet	not available	34009 556 759 1 4	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 160 mg, poudre pour solution buvable en sachet	not available	34009 332 473 7 9	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 300 mg, poudre pour solution buvable en sachet	not available	34009 332 265 5 8	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 300 mg, poudre pour solution buvable en sachet	not available	34009 556 686 4 0	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 500 mg/5 ml, poudre pour solution injectable	not available	34009 353 748 5 1	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 500 mg/5 ml, poudre pour solution injectable	not available	34009 353 747 9 0	SANOFI-AVENTIS FRANCE	FR
KARDEGIC 500 mg/5 ml, poudre pour solution injectable	not available	34009 353 746 2 2	SANOFI-AVENTIS FRANCE	FR

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
KARDEGIC 75 mg, poudre pour solution buvable en sachet-dose	not available	34009 347 441 9 8	SANOFI-AVENTIS FRANCE	FR
Lisaspin 1000, 1800 mg pó para solução oral	not available	9500421	ARISTO PHARMA IBERIA, S.L.	PT
Lisaspin 500, 900 mg pó para solução oral	not available	9500405	ARISTO PHARMA IBERIA, S.L.	PT
MUSKIDOL 1 g/5 ml polvere e solvente per soluzione iniettabile	not available	022620191	OPELLA HEALTHCARE ITALY S.R.L.	IT
MUSKIDOL 1000 mg polvere per soluzione orale	not available	022620239	OPELLA HEALTHCARE ITALY S.R.L.	IT
MUSKIDOL 1000 mg polvere per soluzione orale	not available	022620227	OPELLA HEALTHCARE ITALY S.R.L.	IT
MUSKIDOL 500 mg/2,5 ml polvere e solvente per soluzione iniettabile	not available	022620165	OPELLA HEALTHCARE ITALY S.R.L.	IT