



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2022

EMA/863084/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: eplerenone

Procedure no.: PSUSA/00001236/202203



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
ELECOR 25 mg comprimidos recubiertos con película	not available	66.756	ALMIRALL, S.A.	ES
ELECOR 50 mg comprimidos recubiertos con película	not available	66.757	ALMIRALL, S.A.	ES
Inspra 25 mg filmom obložene tablete	not available	HR-H-730921224	UPJOHN EESV	HR
Inspra 50 mg filmom obložene tablete	not available	HR-H-244093147	UPJOHN EESV	HR
INSPIRA 25 mg comprimate filmate	not available	6919/2014/01	UPJOHN EESV	RO
INSPIRA 25 mg comprimate filmate	not available	6919/2014/03	UPJOHN EESV	RO
INSPIRA 25 mg comprimate filmate	not available	6919/2014/04	UPJOHN EESV	RO
INSPIRA 25 mg comprimate filmate	not available	6919/2014/08	UPJOHN EESV	RO
INSPIRA 25 mg comprimate filmate	not available	6919/2014/10	UPJOHN EESV	RO

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
INSPRA 25 mg comprimate filmate	not available	6919/2014/05	UPJOHN EESV	RO
INSPRA 25 mg comprimate filmate	not available	6919/2014/11	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/02	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/03	UPJOHN EESV	RO
INSPRA 25 mg comprimate filmate	not available	6919/2014/12	UPJOHN EESV	RO
INSPRA 25 mg comprimate filmate	not available	6919/2014/07	UPJOHN EESV	RO
INSPRA 25 mg comprimate filmate	not available	6919/2014/06	UPJOHN EESV	RO
INSPRA 25 mg comprimate filmate	not available	6919/2014/09	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/01	UPJOHN EESV	RO

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
INSPRA 50 mg comprimate filmate	not available	6920/2014/07	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/06	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/08	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/04	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/05	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/11	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/10	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/09	UPJOHN EESV	RO
INSPRA 50 mg comprimate filmate	not available	6920/2014/12	UPJOHN EESV	RO

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
INSpra 25 mg comprimate filmate	not available	6919/2014/02	UPJOHN EESV	RO
Inspra 25 mg filmom obložene tablete	not available	HR-H-730921224	UPJOHN EESV	HR
Inspra 50 mg filmom obložene tablete	not available	HR-H-244093147	UPJOHN EESV	HR
Inspra 25 mg filmom obložene tablete	not available	HR-H-730921224	UPJOHN EESV	HR
Inspra 50 mg filmom obložene tablete	not available	HR-H-244093147	UPJOHN EESV	HR
INSpra 25 mg comprimidos revestidos por película.	NL/H/0506/001	5067616	UPJOHN EESV	PT
Inspra 50 mg filmtabletta	NL/H/0506/002	OGYI-T-20042/04	UPJOHN EESV	HU
Inspra 25 mg filmtabletta	NL/H/0506/001	OGYI-T-20042/03	UPJOHN EESV	HU
Inspra 25 mg Filmtabletten	NL/H/0506/001	2009060410	UPJOHN SRL	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
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/009	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/013	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/019	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/020	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/003	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/021	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/018	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/012	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/030	UPJOHN EESV	SI

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
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/010	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/027	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/017	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/006	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/022	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/008	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/016	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/029	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/014	UPJOHN EESV	SI

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
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/015	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/007	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/002	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/025	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/024	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/005	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/028	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/001	UPJOHN EESV	SI
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/023	UPJOHN EESV	SI

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
Inspra 50 mg filmsko obložene tablete	NL/H/0506/002	H/06/00784/026	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/004	UPJOHN EESV	SI
Inspra 25 mg filmsko obložene tablete	NL/H/0506/001	H/06/00784/011	UPJOHN EESV	SI
Inspra 25 mg filmomhulde tabletten.	NL/H/0506/001	BE270137	UPJOHN SRL	BE
Inspra® 50 mg Filmtabletten	NL/H/0506/002	60328.01.00	VIATRIS PHARMA GMBH	DE
Inspra® 25 mg Filmtabletten	NL/H/0506/001	60328.00.00	VIATRIS PHARMA GMBH	DE
INSpra 50 mg επικαλυμμένα με λεπτό υμένιο δισκία.	NL/H/0506/002	3838/31-1-2013	UPJOHN HELLAS L.T.D.	GR
INSpra 25 mg επικαλυμμένα με λεπτό υμένιο δισκία.	NL/H/0506/001	3837/31-1-2013	UPJOHN HELLAS L.T.D.	GR
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298231	VIATRIS PHARMA 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
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298041	VIATRIS PHARMA S.R.L.	IT
Inspra® 50 mg Filmtabletten	NL/H/0506/002	1-25567	UPJOHN EESV	AT
INSPIRA 25 mg filmhúðaðar töflur.	NL/H/0506/001	IS/1/04/036/01	UPJOHN EESV	IS
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298256	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298130	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298039	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298155	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298167	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298027	VIATRIS PHARMA 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
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298270	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg filmdragerade tabletter.	NL/H/0506/001	21030	UPJOHN EESV	SE
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298142	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298092	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg filmdrasjerte tabletter	NL/H/0506/002	04-2665	UPJOHN EESV	NO
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298066	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298282	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298104	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298181	VIATRIS PHARMA 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
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298015	VIATRIS PHARMA S.R.L.	IT
INSPIRA 50 mg filmuhúðaðar töflur.	NL/H/0506/002	IS/1/04/036/02	UPJOHN EESV	IS
Inspra 50 mg filmdragerade tabletter.	NL/H/0506/002	21031	UPJOHN EESV	SE
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298116	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298193	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298217	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298179	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298128	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg filmtabletta	NL/H/0506/002	OGYI-T-20042/02	UPJOHN EESV	HU

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
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298243	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298229	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg filmtabletta	NL/H/0506/001	OGYI-T-20042/01	UPJOHN EESV	HU
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298054	VIATRIS PHARMA S.R.L.	IT
Inspra 50 mg comprimidos recubiertos con película	NL/H/0506/002	66355	VIATRIS HEALTHCARE S.L.	ES
Inspra 25 mg filmdrasjerte tabletter	NL/H/0506/001	04-2664	UPJOHN EESV	NO
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298268	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298078	VIATRIS PHARMA S.R.L.	IT
Inspra 25 mg compresse rivestite con film	NL/H/0506/001	037298080	VIATRIS PHARMA 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
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5027461	UPJOHN EESV	PT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5027453	UPJOHN EESV	PT
INSPRA, 50 mg, tabletki powlekane	NL/H/0506/002	12291	UPJOHN EESV	PL
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169784	UPJOHN EESV	PT
INSPRA, 25 mg, tabletki powlekane	NL/H/0506/001	12290	UPJOHN EESV	PL
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169586	UPJOHN EESV	PT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5169180	UPJOHN EESV	PT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5168786	UPJOHN EESV	PT
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169883	UPJOHN EESV	PT

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
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5170089	UPJOHN EESV	PT
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169487	UPJOHN EESV	PT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5168885	UPJOHN EESV	PT
Inspra 50 mg compresse rivestite con film	NL/H/0506/002	037298205	VIATRIS PHARMA S.R.L.	IT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5169289	UPJOHN EESV	PT
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5169388	UPJOHN EESV	PT
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169685	UPJOHN EESV	PT
Inspra, filmovertrukne tabletter	NL/H/0506/001	36569	UPJOHN EESV	DK
Inspra® 25 mg Filmdtabletten	NL/H/0506/001	1-25566	UPJOHN EESV	AT

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
INSPRA 50 mg filmom obalené tablety	NL/H/0506/002	50/0072/06-S	UPJOHN EESV	SK
INSPRA 50 mg comprimidos revestidos por película.	NL/H/0506/002	5169982	UPJOHN EESV	PT
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 566 162 8 2	PFIZER PFE FRANCE	FR
Inspra, filmovertrukne tabletter	NL/H/0506/002	36570	UPJOHN EESV	DK
INSPRA 25 mg επικαλυμμένα με λεπτό υμένιο δισκία.	NL/H/0506/001	20103	UPJOHN HELLAS L.T.D.	CY
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 366 573 4 2	PFIZER PFE FRANCE	FR
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5168984	UPJOHN EESV	PT
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 366 574 0 3	PFIZER PFE FRANCE	FR
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 566 161 1 4	PFIZER PFE 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
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 366 571 1 3	PFIZER PFE FRANCE	FR
INSPRA 25 mg comprimidos revestidos por película.	NL/H/0506/001	5169081	UPJOHN EESV	PT
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 566 160 5 3	PFIZER PFE FRANCE	FR
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 366 572 8 1	PFIZER PFE FRANCE	FR
INSPRA 50 mg, comprimé pelliculé	NL/H/0506/002	34009 390 994 6 0	PFIZER PFE FRANCE	FR
Inspra 25 mg comprimidos recubiertos con película	NL/H/0506/001	66356	VIATRIS HEALTHCARE S.L.	ES
INSPRA 25 mg filmom obalené tablety	NL/H/0506/001	50/0071/06-S	UPJOHN EESV	SK
INSPRA 50 mg potahované tablety	NL/H/0506/002	34/012/06-C	UPJOHN EESV	CZ
INSPRA 50 mg kalvopäällysteiset tabletit	NL/H/0506/002	19485	UPJOHN EESV	FI

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
INSpra 50 mg επικαλυμμένα με λεπτό υμένιο δισκία.	NL/H/0506/002	20104	UPJOHN HELLAS L.T.D.	CY
Inspra 50 mg comprimés pelliculés.	NL/H/0506/002	2009060411	UPJOHN SRL	LU
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 366 170 7 0	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 566 159 7 1	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 366 570 5 2	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 366 173 6 0	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 366 171 3 1	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 566 158 0 3	PFIZER PFE FRANCE	FR
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 390 981 1 1	PFIZER PFE 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
INSpra 25 mg, comprimé pelliculé	NL/H/0506/001	34009 566 157 4 2	PFIZER PFE FRANCE	FR
INSpra 50, filmomhulde tabletten 50 mg.	NL/H/0506/002	RVG 29964	VIATRIS NETHERLANDS B.V.	NL
INSpra 25, filmomhulde tabletten 25 mg.	NL/H/0506/001	RVG 29963	VIATRIS NETHERLANDS B.V.	NL
INSpra 25 mg film-coated tablets.	NL/H/0506/001	PL 50622/0028	UPJOHN UK LIMITED	XI
INSpra 50 mg film-coated tablets.	NL/H/0506/002	PL 50622/0029	UPJOHN UK LIMITED	XI
Inspra 50 mg comprimés pelliculés.	NL/H/0506/002	BE270121	UPJOHN SRL	BE
Inspra 25 mg filmdragerade tabletter.	NL/H/0506/001	19484	UPJOHN EESV	FI
INSpra 50 mg film-coated tablets.	NL/H/0506/002	PA 23055/005/002	UPJOHN EESV	IE
INSpra 25 mg film-coated tablets.	NL/H/0506/001	PA 23055/005/001	UPJOHN EESV	IE