8 March 2018
EMA/182904/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): fluticasone propionate / formoterol fumarate dihydrate

Procedure No.: PSUSA/00010339/201707

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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
Abriff 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/002	042292021/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/002	042292021	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 125 microgramos/5 microgramos inhalación suspensión para inhalación en envase a presión	UK/H/4379/002	78679	MUNDIPHARMA PHARMACEUTICALS SL	ES
Abriff 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/003	042292033/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/003	042292033	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 250 microgramos/10 microgramos inhalación, suspensión para inhalación en envase a	UK/H/4379/003	78678	MUNDIPHARMA PHARMACEUTICALS SL	ES

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
presión				
Abriff 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/001	042292019/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4379/001	042292019	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 50 microgramos/5 microgramos inhalación, suspensión para inhalación en envase a presión	UK/H/4379/001	78677	MUNDIPHARMA PHARMACEUTICALS SL	ES
Abriff® 125 microgram/5 microgram per actuation pressurised inhalation, suspension	UK/H/4379/002	PL 16950/0189	NAPP PHARMACEUTICALS LTD	UK
Abriff® 250 microgram/10 micro gram per actuation pressurised inhalation, suspension	UK/H/4379/003	PL 16950/0190	NAPP PHARMACEUTICALS LTD	UK
Abriff® 50 microgram/5 microgr am per actuation pressurised inhalation, suspension	UK/H/4379/001	PL 16950/0188	NAPP PHARMACEUTICALS LTD	UK
AFFERA 125 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon	UK/H/4378/002	34009 266 488 5 5	MUNDIPHARMA	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
pressurisé				
Affera 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4378/002	042293023/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Affera 125 microgramos/5 microgramos inhalación, suspensión para inhalación en envase a presión	UK/H/4378/002	79144	MUNDIPHARMA PHARMACEUTICALS SL	ES
AFFERA 250 microgrammes/10 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/4378/003	34009 266 489 1 6	MUNDIPHARMA	FR
Affera 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4378/003	042293035/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Affera 250 microgramos/10 microgramos inhalación, suspensión para inhalación en envase a presión	UK/H/4378/003	79145	MUNDIPHARMA PHARMACEUTICALS SL	ES
AFFERA 50 microgrammes/5 microgrammes par dose, suspension pour	UK/H/4378/001	34009 266 487 9 4	MUNDIPHARMA	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
inhalation en flacon pressurisé				
Affera 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/4378/001	042293011/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Affera 50 microgramos/5 microgramos inhalación, suspensión para inhalación en envase a presión	UK/H/4378/001	79146	MUNDIPHARMA PHARMACEUTICALS SL	ES
affera® 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/4378/002	81904.00.00	MUNDIPHARMA GMBH	DE
Affera® 125 microgram/5 microg ram per actuation pressurised inhalation, suspension	UK/H/4378/002	PL 16950/0186	NAPP PHARMACEUTICALS LTD	UK
affera® 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/4378/003	81905.00.00	MUNDIPHARMA GMBH	DE
Affera® 250 microgram/10 micro gram per actuation pressurised inhalation, suspension	UK/H/4378/003	PL 16950/0187	NAPP PHARMACEUTICALS LTD	UK
affera® 50	UK/H/4378/001	81903.00.00	MUNDIPHARMA GMBH	DE

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
Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension				
Affera® 50 microgram/5 microgram per actuation pressurised inhalation, suspension	UK/H/4378/001	PL 16950/0185	NAPP PHARMACEUTICALS LTD	UK
Flutiform 125 mcg/5 mcg , suspension pour inhalation en flacon pressurisé	UK/H/2872/001-003/DC	2013040097	MUNDIPHARMA COMM VA	LU
Flutiform 125 microgram l 5 microgram , aerosol, suspensie	UK/H/2872/002	BE429414	MUNDIPHARMA COMM VA	BE
Flutiform 125 microgram/ 5 microgram l dosis aerosol, suspensie	UK/H/2872/001	RVG 107242	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension	UK/H/2872/002	PA 1688/13/2	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Flutiform 125 microgame /5 microgame suspensie de inhalat presurizată	UK/H/2872/002	5438/2013/01	MUNDIPHARMA GES.M.B.H	RO
Flutiform 125 microgrammes/5 microgrammes , suspension pour inhalation en flacon	UK/H/2872/002	BE429414	MUNDIPHARMA COMM VA	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
pressurisé				
FLUTIFORM 125 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/2872/002	34009 266 488 5 5	MUNDIPHARMA	FR
Flutiform 125 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión	UK/H/2872/002	78536	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 125 mikrogram/ 5 mikrogram per dose, inhalasjonsaerosol, suspensjon	UK/H/2872/002	10-7475	MUNDIPHARMA AS.	NO
Flutiform 125 mikrogram/5 mikrogram per puff, inhalationsspray, suspension	UK/H/2872/002	44065	MUNDIPHARMA AB	SE
Flutiform 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/002	1-31520	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
Flutiform 125 mikrogramov/5 mikrogramov	UK/H/2872/002	14/0357/12-S	MUNDIPHARMA GES.M.B.H	SK
Flutiform 125 mikrogramů/5 mikrogramů v jedné	UK/H/2872/002	14/554/12-C	MUNDIPHARMA GES.M.B.H	CZ

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
dávce, suspenze k inhalaci v tlakovém obalu				
Flutiform 125 microgramas/5 micr ogramas suspensão pressurizada para inalação	UK/H/2872/002	5488234	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Flutiform 125 mikrog/5 mikrog/an nos Inhalaatiosumute, suspensio	UK/H/2872/002	28589	MUNDIPHARMA OY	FI
Flutiform 125 míkrógrömm/5 míkr ógrömm í úðaskammti innúðalyf, dreifa	UK/H/2872/002	IS/1/12/096/02	NORPHARMA A/S	IS
Flutiform 125 μικρογραμμάρια/5 μικρογραμμάρια ανά ψεκασμό, εναιώρημα για εισπνοή υπό πίεση	UK/H/2872/002	21396	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 250 mcg/10 mcg , suspension pour inhalation en flacon pressurisé.	UK/H/2872/001-003/DC	2013040098	MUNDIPHARMA COMM VA	LU
Flutiform 250 microgram / 10 microgram I dosis aerosol, suspensie	UK/H/2872/003	RVG 107243	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform 250 microgram I 10 microgram , aerosol, suspensie	UK/H/2872/003	BE429423	MUNDIPHARMA COMM VA	BE
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension	UK/H/2872/003	PA 1688/13/3	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE

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
Flutiform 250 micrograme/10 micrograme suspensie de inhalat presurizata	UK/H/2872/003	5439/2013/01	MUNDIPHARMA GES.M.B.H	RO
Flutiform 250 microgrammes/10 microgrammes , suspension pour inhalation en flacon pressurisé	UK/H/2872/003	BE429423	MUNDIPHARMA COMM VA	BE
FLUTIFORM 250 microgrammes/10 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/2872/003	34009 266 489 1 6	MUNDIPHARMA	FR
Flutiform 250 microgramos/10 microgramos/inhalación, suspensión para inhalación en envase a presión	UK/H/2872/003	78537	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 250 mikrogram/ 10 mikrogram per dose, inhalasjonsaerosol, suspensjon	UK/H/2872/003	10-7476	MUNDIPHARMA AS.	NO
Flutiform 250 mikrogram/10 mikrogram	UK/H/2872/003	14/0358/12-S	MUNDIPHARMA GES.M.B.H	SK
Flutiform 250 mikrogram/10 mikrogram per puff, inhalationsspray, suspension	UK/H/2872/003	44066	MUNDIPHARMA AB	SE

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
Flutiform 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/003	1-31521	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
Flutiform 250 mikrogramů/10 mikrogramů v jedné dávce, suspenze k inhalaci v tlakovém obalu	UK/H/2872/003	14/555/12-C	MUNDIPHARMA GES.M.B.H	CZ
Flutiform 250 microgramas/10 microgramas suspensão pressurizada para inalação	UK/H/2872/003	5488242	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Flutiform 250 mikrog/10 mikrog/annos Inhalaatiosumute, suspensio	UK/H/2872/003	28590	MUNDIPHARMA OY	FI
Flutiform 250 míkrógrömm/10 míkrógrömm í úðaskammti innúðalyf, dreifa	UK/H/2872/003	IS/1/12/096/03	NORPHARMA A/S	IS
Flutiform 250 μικρογραμμάρια/10 μικρογραμμάρια ανά ψεκασμό, εναιώρημα για εισπνοή υπό πίεση	UK/H/2872/003	21397	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 50 mcg/5 mcg , suspension pour inhalation en flacon pressurisé	UK/H/2872/001-003	2013040096	MUNDIPHARMA COMM VA	LU
Flutiform 50 microgram / 5 microgram , aërosol,	UK/H/2872/001	BE429405	MUNDIPHARMA COMM VA	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
suspensie				
Flutiform 50 microgram I 5 microgram I dosis aerosol, suspensie	UK/H/2872/001	RVG 107222	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform 50 microgram/5 microgram per metered dose pressurised inhalation, suspension	UK/H/2872/001	PA 1688/13/1	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Flutiform 50 micrograme /5 micrograme suspensie de inhalat presurizată	UK/H/2872/001	5437/2013/01	MUNDIPHARMA GES.M.B.H	RO
Flutiform 50 microgrammes/5 microgrammes , suspension pour inhalation en flacon pressurisé	UK/H/2872/001	BE429405	MUNDIPHARMA COMM VA	BE
FLUTIFORM 50 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/2872/001	34009 266 487 9 4	MUNDIPHARMA	FR
Flutiform 50 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión	UK/H/2872/001/E/001	78538	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 50 mikrogram/ 5 mikrogram per dose, inhalasjonsaerosol, suspensjon	UK/H/2872/001	10-7474	MUNDIPHARMA AS.	NO
Flutiform 50	UK/H/2872/001	44064	MUNDIPHARMA AB	SE

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
mikrogram/5 mikrogram per puff, inhalationsspray, suspension				
Flutiform 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/001	1-31519	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
Flutiform 50 mikrogramov/5 mikrogramov	UK/H/2872/001	14/0356/12-S	MUNDIPHARMA GES.M.B.H	SK
Flutiform 50 mikrogramů/5 mikrogramů v jedné dávce, suspenze k inhalaci v tlakovém obalu	UK/H/2872/001	14/553/12-C	MUNDIPHARMA GES.M.B.H	CZ
Flutiform 50 μικρογραμμάρια/5 μικρογραμμάρια ανά ψεκασμό, εναιώρημα για εισπνοή υπό πίεση.	UK/H/2872/001	21395	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 50 microgramas/5 micro gramas suspensão pressurizada para inalação	UK/H/2872/001	5488226	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Flutiform 50 mikrog/5 mikrog/ann os Inhalaatiosumute, suspensio	UK/H/2872/001	28588	MUNDIPHARMA OY	FI
Flutiform 50 míkrógrömm/5 míkró grömm í úðaskammti	UK/H/2872/001	IS/1/12/096/01	NORPHARMA A/S	IS

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
innúðalyf, dreifa				
Flutiform, (125 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina	UK/H/2872/002	20713	NORPHARMA A/S	PL
Flutiform, (250 mikrogramów + 10 mikrogramów)/dawkę inhalacyjną, aerozol inhalacyjny, zawiesina	UK/H/2872/003	20714	NORPHARMA A/S	PL
Flutiform, (50 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina	UK/H/2872/001	20712	NORPHARMA A/S	PL
Flutiform, inhalationsspray, suspension	UK/H/2872/003	46691	NORPHARMA A/S	DK
Flutiform, inhalationsspray, suspension	UK/H/2872/002	46690	NORPHARMA A/S	DK
Flutiform, inhalationsspray, suspension	UK/H/2872/001	46689	NORPHARMA A/S	DK
Flutiform® 125 microgram/5 microgram per actuation pressurised inhalation, suspension	UK/H/2872/002	PL 16950/0168	NAPP PHARMACEUTICALS LTD	UK
flutiform® 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/002	81898.00.00	MUNDIPHARMA GMBH	DE

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
Flutiform® 250 microgram/10 microgram per actuation pressurised inhalation, suspension.	UK/H/2872/003	PL 16950/0190	NAPP PHARMACEUTICALS LTD	UK
flutiform® 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/003	81899.00.00	MUNDIPHARMA GMBH	DE
Flutiform® 50 microgram/5 microgram per actuation pressurised inhalation, suspension	UK/H/2872/001	PL 16950/0167	NAPP PHARMACEUTICALS LTD	UK
flutiform® 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension	UK/H/2872/001	81897.00.00	MUNDIPHARMA GMBH	DE
Flutiformo 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/2872/002	042294025	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/2872/002	042294052	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 250 microgrammi/10	UK/H/2872/003	042294064	MUNDIPHARMA PHARMACEUTICALS SRL	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
microgrammi per erogazione, sospensione pressurizzata per inalazione				
Flutiformo 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/2872/003	042294037	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/2872/001	042294013	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione	UK/H/2872/001	042294049	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Iffeza 125 microgram / 5 microgram per dosis, aerosol, suspensie	UK/H/4015/002	BE432031	MUNDIPHARMA COMM VA	BE
Iffeza 125 microgrammes/5 microgrammes , suspension pour inhalation en flacon pressurisé	UK/H/4015/002	BE432031	MUNDIPHARMA COMM VA	BE
IFFEZA 125 microgrammes/5 microgrammes par dose, suspension pour	UK/H/4015/002	34009 266 488 5 5	MUNDIPHARMA	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
inhalation en flacon pressurisé				
Iffeza 250 microgram / 10 microgram per dosis, aerosol, suspensie	UK/H/4015/003	BE432047	MUNDIPHARMA COMM VA	BE
Iffeza 250 microgrammes/10 microgrammes , suspension pour inhalation en flacon pressurisé	UK/H/4015/003	BE432047	MUNDIPHARMA COMM VA	BE
IFFEZA 250 microgrammes/10 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/4015/003	34009 266 489 1 6	MUNDIPHARMA	FR
Iffeza 50 microgram / 5 microgram per dosis, aerosol, suspensie	UK/H/4015/001	BE432022	MUNDIPHARMA COMM VA	BE
Iffeza 50 microgrammes/5 microgrammes , suspension pour inhalation en flacon pressurisé	UK/H/4015/001	BE432022	MUNDIPHARMA COMM VA	BE
IFFEZA 50 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé	UK/H/4015/001	34009 266 487 9 4	MUNDIPHARMA	FR
ФЛУТИФОРМ 125 микрограма/5 микрограма на	UK/H/2872/002/DC	20120518	MUNDIPHARMA GES.M.B.H	BG

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
впръскване, суспензия под налягане за инхалация				
ФЛУТИФОРМ 250 микрограма/10 микрограма на впръскване, суспензия под налягане за инхалация	UK/H/2872/003/DC	20120519	MUNDIPHARMA GES.M.B.H	BG
ФЛУТИФОРМ 50 микрограма/5 микрограма на впръскване, суспензия под налягане за инхалация	UK/H/2872/001/DC	20120517	MUNDIPHARMA GES.M.B.H	BG