



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 March 2016
EMA/346216/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: fluticasone propionate / formoterol fumarate dihydrate

Procedure no.: PSUSA/00010339/201507



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 mikrogram/10 mikrogram per puff, inhalationsspray, suspension		44066	MUNDIPHARMA AB	SE
Flutiform 50 mikrogram/5 mikrogram per puff, inhalationsspray, suspension		44064	MUNDIPHARMA AB	SE
Flutiform 125 mikrogram/5 mikrogram per puff, inhalationsspray, suspension		44065	MUNDIPHARMA AB	SE
Flutiformo 125 mcg/5 mcg per erogazione, sospensione pressurizzata per inalazione		42294052	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione		AIC N.042294064/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		AIC N.042294049/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiform® 125 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0168	NAPP PHARMACEUTICALS LTD	GB
Abriff® 125 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0189	NAPP PHARMACEUTICALS LTD	GB
Abriff® 250 microgram/10 microgram per actuation pressurised inhalation, suspension		PL 16950/0190	NAPP PHARMACEUTICALS LTD	GB

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® 50 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0188	NAPP PHARMACEUTICALS LTD	GB
Abriff 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292019/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiform 250 microgramos/10 microgramos/inhalación, suspensión para inhalación en envase a presión		78537	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 125 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		78536	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform, (50 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina		20712	NORPHARMA A/S	PL
Flutiform, (125 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina		20713	NORPHARMA A/S	PL
Abriff 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292033/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
AFFERA 125 microgrammes/5 microgrammes par dose,		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
suspension pour inhalation en flacon pressurisé				
Abriff 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292021/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Abriff 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292033/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
affera® 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81903.00.00	MUNDIPHARMA GMBH	DE
affera® 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81904.00.00	MUNDIPHARMA GMBH	DE
Flutiform 50 microgram/5 microgram per metered dose pressurised inhalation, suspension		PA 1688/13/1	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
FLUTIFORM 50 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé		34009 266 487 9 4	MUNDIPHARMA	FR
Flutiform 125 micrograme /5 micrograme suspensie de inhalat presurizat?		5438/2013/01	MUNDIPHARMA GES.M.B.H	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
Flutiform 250 micrograme/10 micrograme suspensie de inhalat presurizata		5439/2013/01	MUNDIPHARMA GES.M.B.H	RO
Flutiform 50 micrograme /5 micrograme suspensie de inhalat presurizat?		5437/2013/01	MUNDIPHARMA GES.M.B.H	RO
Abriff 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292019/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiform® 50 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0167	NAPP PHARMACEUTICALS LTD	GB
Flutiform, inhalationsspray, suspension		46690	NORPHARMA A/S	DK
Flutiform, inhalationsspray, suspension		46689	NORPHARMA A/S	DK
Affera® 125 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0186	NAPP PHARMACEUTICALS LTD	GB
Affera® 50 microgram/5 microgram per actuation pressurised inhalation, suspension		PL 16950/0185	NAPP PHARMACEUTICALS LTD	GB

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
Flutiformo 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042294025/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiformo 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione		042294037/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Affera® 250 microgram/10 microgram per actuation pressurised inhalation, suspension		PL 16950/0187	NAPP PHARMACEUTICALS LTD	GB
FLUTIFORM 250 microgrammes/10 microgrammes par dose, suspension pour inhalation en flacon pressurisé		34009 266 489 1 6	MUNDIPHARMA	FR
FLUTIFORM 125 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé		34009 266 488 5 5	MUNDIPHARMA	FR
Flutiform, (250 mikrogramów + 10 mikrogramów)/dawk? inhalacyjn?, aerosol inhalacyjny, zawiesina		20714	NORPHARMA A/S	PL
Flutiformo 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042294013/M	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
Flutiform 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		1-31519	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
affera® 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81905.00.00	MUNDIPHARMA GMBH	DE
flutiform® 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81898.00.00	MUNDIPHARMA GMBH	DE
AFFERA 50 microgrammes/5 microgrammes par dose, suspension pour inhalation en flacon pressurisé		34009 266 487 9 4	MUNDIPHARMA	FR
AFFERA 250 microgrammes/10 microgrammes par dose, suspension pour inhalation en flacon pressurisé		34009 266 489 1 6	MUNDIPHARMA	FR
flutiform® 50 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81897.00.00	MUNDIPHARMA GMBH	DE
Flutiform 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		1-31521	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
Affera 250 microgrammi/10 microgrammi per erogazione, sospensione pressurizzata per inalazione		042293035/M	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
Flutiform 125 Mikrogramm/5 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		1-31520	MUNDIPHARMA GESELLSCHAFT M.B.H.	AT
flutiform® 250 Mikrogramm/10 Mikrogramm pro Sprühstoß Druckgasinhalation, Suspension		81899.00.00	MUNDIPHARMA GMBH	DE
Affera 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042293023/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Affera 50 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042293011/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiform 250 μικρογραμμ?ρια/10 μικρογραμμ?ρια αν? ψεκασμ?, εναι?ρημα για εισπνο? υπ? π?εση		21397	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 250 mikrogram?/10 mikrogram? v jedné dávce, suspenze k inhalaci v tlakovém obalu		14/555/12-C	MUNDIPHARMA GES.M.B.H	CZ
Flutiform® 250 microgram/10 microgram per actuation pressurised inhalation, suspension.		PL 16950/0190	NAPP PHARMACEUTICALS LTD	GB
Flutiform 125 mikrogram?/5 mikrogram? v jedné dávce, suspenze k inhalaci v tlakovém		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
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Flutiform 50 μικρογραμμ?ρια/5 μικρογραμμ?ρια αν? ψεκασμ?, εναι?ρημα για εισπνο? υπ? π?εση.		21395	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension		PA 1688/13/2	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension		PA 1688/13/3	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Flutiform 125 mikrogramov/5 mikrogramov		14/0357/12-S	MUNDIPHARMA GES.M.B.H	SK
Flutiform 50 mikrogramov/5 mikrogramov		14/0356/12-S	MUNDIPHARMA GES.M.B.H	SK
Flutiform, inhalationsspray, suspension		46691	NORPHARMA A/S	DK
Flutiform 250 microgramas/10 microgramas suspensão pressurizada para inalação		5488242	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Flutiform 50 microgramas/5 microgramas suspensão pressurizada para inalação		5488226	MUNDIPHARMA PHARMACEUTICALS LTD	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
Flutiform 125 microgramas/5 microgramas suspensão pressurizada para inalação		5488234	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Flutiform 50 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		78538	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 50 mikrogram?/5 mikrogram? v jedné dávce, suspenze k inhalaci v tlakovém obalu		14/553/12-C	MUNDIPHARMA GES.M.B.H	CZ
Flutiform 125 μικρογραμμ?ρια/5 μικρογραμμ?ρια αν? ψεκασμ?, εναι?ρημα για εισπνο? υπ? π?εση		21396	MUNDIPHARMA PHARMACEUTICALS LTD	CY
Flutiform 50 míkrogrömm/5 míkrogrömm í úðaskammti innúðalyf, dreifa		IS/1/12/096/01	NORPHARMA A/S	IS
Flutiform 250 míkrogrömm/10 míkrogrömm í úðaskammti innúðalyf, dreifa		IS/1/12/096/03	NORPHARMA A/S	IS
Flutiform 125 míkrogrömm/5 míkrogrömm í úðaskammti innúðalyf, dreifa		IS/1/12/096/02	NORPHARMA A/S	IS
Flutiform 250 microgrammes/10 microgrammes , suspension pour inhalation en flacon pressurisé		BE429423	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
Flutiform 125 microgrammes/5 microgrammes , suspension pour inhalation en flacon pressurisé		BE429414	MUNDIPHARMA COMM VA	BE
Flutiform 50 microgrammes/5 microgrammes , suspension pour inhalation en flacon pressurisé		BE429405	MUNDIPHARMA COMM VA	BE
Abriff 125 microgrammi/5 microgrammi per erogazione, sospensione pressurizzata per inalazione		042292021/M	MUNDIPHARMA PHARMACEUTICALS SRL	IT
Flutiform 250 mikrogram/10 mikrogram		14/0358/12-S	MUNDIPHARMA GES.M.B.H	SK
Abriff 125 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		78679	MUNDIPHARMA PHARMACEUTICALS SL	ES
Abriff 50 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		78677	MUNDIPHARMA PHARMACEUTICALS SL	ES
Affer 50 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		79146	MUNDIPHARMA PHARMACEUTICALS SL	ES
Flutiform 125 mikrog/5 mikrog/annos Inhalaatiosumute, suspensio		28589	MUNDIPHARMA OY	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
Flutiform 250 mikrog/10 mikrog/annos Inhalaatiosumute, suspensio		28590	MUNDIPHARMA OY	FI
Flutiform 50 mikrog/5 mikrog/annos Inhalaatiosumute, suspensio		28588	MUNDIPHARMA OY	FI
Flutiform 250 mikrogram / 10 mikrogram per dose, inhalasjonsaerosol, suspensjon		Oct-76	MUNDIPHARMA AS.	NO
Flutiform 50 mikrogram / 5 mikrogram per dose, inhalasjonsaerosol, suspensjon		Oct-74	MUNDIPHARMA AS.	NO
Flutiform 125 mikrogram / 5 mikrogram per dose, inhalasjonsaerosol, suspensjon		Oct-75	MUNDIPHARMA AS.	NO
Abriff 250 microgramos/10 microgramos/inhalación, suspensión para inhalación en envase a presión		78678	MUNDIPHARMA PHARMACEUTICALS SL	ES
Affer 250 microgramos/10 microgramos/inhalación, suspensión para inhalación en envase a presión		79145	MUNDIPHARMA PHARMACEUTICALS SL	ES
Affer 125 microgramos/5 microgramos/inhalación, suspensión para inhalación en envase a presión		79144	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
Flutiform125 microgram / 5 microgram / dosis aërosol, suspensie		RVG 107242	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform50 microgram / 5 microgram / dosis aërosol, suspensie		RVG 107222	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform250 microgram / 10 microgram / dosis aërosol, suspensie		RVG 107243	MUNDIPHARMA PHARMACEUTICALS BV	NL
Flutiform 125 microgram / 5 microgram , aërosol, suspensie		BE429414	MUNDIPHARMA COMM VA	BE
Flutiform 250 microgram / 10 microgram , aërosol, suspensie.		BE429423	MUNDIPHARMA COMM VA	BE
Flutiform 50 microgram / 5 microgram , aërosol, suspensie		BE429405	MUNDIPHARMA COMM VA	BE
Iffeza 250 microgramas/10 microgramas suspensão pressurizada para inalação		5488275	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Iffeza 50 microgramas/5 microgramas suspensão pressurizada para inalação		5488259	MUNDIPHARMA PHARMACEUTICALS LTD	PT
Iffeza 125 microgramas/5 microgramas suspensão pressurizada para		5488267	MUNDIPHARMA PHARMACEUTICALS LTD	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
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Flutiform, (50 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina		20712	NORPHARMA A/S	PL
Flutiform, (125 mikrogramów + 5 mikrogramów)/dawke inhalacyjna, aerozol inhalacyjny, zawiesina		20713	NORPHARMA A/S	PL
Flutiform, (250 mikrogramów + 10 mikrogramów)/dawk? inhalacyjn?, aerozol inhalacyjny, zawiesina		20714	NORPHARMA A/S	PL
Iffeza		20757	Norpharma A/S	PL
Iffeza		20756	Norpharma A/S	PL
Iffeza		20758	Norpharma A/S	PL