



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 April 2025
EMA/128781/2025
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ciclesonide

Procedure No. PSUSA/00000742/202408



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
Alvesco 160 Mikrogramm - Dosieraerosol	SE/H/1861/002	1-27508	COVIS PHARMA EUROPE B.V.	AT
Alvesco 80 Mikrogramm - Dosieraerosol	SE/H/1861/001	1-27507	COVIS PHARMA EUROPE B.V.	AT
Ciclesonid Genetic 160 Mikrogramm/Sprühstoß Druckgasinhalation, Lösung	AT/H/1266/001	142203	GENETIC SPA	AT
Ciclesonid Genetic 320 Mikrogramm/Sprühstoß Druckgasinhalation, Lösung	AT/H/1266/001	142204	GENETIC SPA	AT
Ciclesonid Genetic 80 Mikrogramm/Sprühstoß Druckgasinhalation, Lösung	AT/H/1266/001	142202	GENETIC SPA	AT
CicloBronch 160 Mikrogramm/Dosis Druckgasinhalation, Lösung	AT/H/1343/001	142152	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	AT
Алвеско 160 микрограма, разтвор под налягане за инхалации.	SE/H/1861/002	20080173	COVIS PHARMA EUROPE B.V.	BG
Алвеско 80 микрограма, разтвор под налягане за инхалация.	SE/H/1861/001	20080172	COVIS PHARMA EUROPE B.V.	BG
Циклозид 160 микрограма на впръскване, разтвор под налягане за инхалация	AT/H/1267/002	20230216	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	BG
Циклозид 320 микрограма на впръскване, разтвор	AT/H/1267/003	20230217	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	BG

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под налягане за инхалация				
Циклозид 80 микрограма на впръскване, разтвор под налягане за инхалация	AT/H/1267/001	20230215	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	BG
Alvesco 160 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/002	20456	COVIS PHARMA EUROPE B.V.	CY
Alvesco 80 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/001	20455	COVIS PHARMA EUROPE B.V.	CY
Alvesco 160 mikrogramů/dávka roztok k inhalaci v tlakovém obalu	SE/H/1861/002	14/003/05-C	COVIS PHARMA EUROPE B.V.	CZ
Ciclesonide Polpharma 160 mikrogramů/dávka roztok k inhalaci v tlakovém obalu	AT/H/1267/002	4/509/21-C	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	CZ
Ciclesonide Polpharma 320 mikrogramů/dávka roztok k inhalaci v tlakovém obalu	AT/H/1267/003	4/510/21-C	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	CZ
Ciclesonide Polpharma 80 mikrogramů/dávka roztok k inhalaci v tlakovém obalu	AT/H/1267/001	14/508/21-C	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	CZ
Alvesco 160 Mikrogramm Druckgasinhalation, Lösung	SE/H/1861/002	60978.02.00	COVIS PHARMA EUROPE B.V.	DE
Alvesco® 80 Mikrogramm Druckgasinhalation, Lösung	SE/H/1861/001	60978.01.00	COVIS PHARMA EUROPE B.V.	DE
CicloBronch 160 Mikrogramm/Dosis	AT/H/1343/001	7009100.00.00	INFECTOPHARM ARZNEIMITTEL UND	DE

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Druckgasinhalation, Lösung			CONSILIUM GMBH	
Alvesco, inhalationsspray, opløsning 160 mikrogram/dosis	SE/H/1861/002	37078	COVIS PHARMA EUROPE B.V.	DK
Alvesco, inhalationsspray, opløsning 80 mikrogram/dosis	SE/H/1861/001	37077	COVIS PHARMA EUROPE B.V.	DK
Ciclesonide "Sandoz", inhalationsspray, opløsning	NL/H/5651/001	68201	SANDOZ A/S	DK
Ciclesonide "Sandoz", inhalationsspray, opløsning	NL/H/5651/002	68202	SANDOZ A/S	DK
Alvesco 160 microgramos/inhalación solución para inhalación en envase a presión	SE/H/1861/02	70372	COVIS PHARMA EUROPE B.V.	ES
Alvesco 160 mikrog/annos inhalaatiosumute, liuos	SE/H/1861/002	19859	COVIS PHARMA EUROPE B.V.	FI
Alvesco 160 mikrogram/dos inhalationsspray, lösning	SE/H/1861/002	19859	COVIS PHARMA EUROPE B.V.	FI
Alvesco 80 mikrog/annos inhalaatiosumute, liuos	SE/H/1861/001	19858	COVIS PHARMA EUROPE B.V.	FI
Alvesco 80 mikrogram/dos inhalationsspray, lösning	SE/H/1861/001	19858	COVIS PHARMA EUROPE B.V.	FI
Ciclesonide Sandoz 160 mikrog/annos inhalaatiosumute, liuos	NL/H/5651/002	41397	SANDOZ A/S	FI
Ciclesonide Sandoz 80 mikrog/annos inhalaatiosumute, liuos	NL/H/5651/001	41396	SANDOZ A/S	FI
ALVESCO 160 microgrammes/dose,	SE/H/1861/002	34009 390 028 2 8	COVIS PHARMA EUROPE B.V.	FR

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solution pour inhalation en flacon pressurisé				
ALVESCO 160 microgrammes/dose, solution pour inhalation en flacon pressurisé	SE/H/1861/002	34009 390 029 9 6	COVIS PHARMA EUROPE B.V.	FR
ALVESCO 160 microgrammes/dose, solution pour inhalation en flacon pressurisé	SE/H/1861/002	34009 390 030 7 8	COVIS PHARMA EUROPE B.V.	FR
ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressurisé	SE/H/1861/001	34009 390 024 7 7	COVIS PHARMA EUROPE B.V.	FR
ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressurisé	SE/H/1861/001	34009 390 025 3 8	COVIS PHARMA EUROPE B.V.	FR
ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressurisé	SE/H/1861/001	34009 390 027 6 7	COVIS PHARMA EUROPE B.V.	FR
Alvesco 160 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/002	2994/14-1-2021	COVIS PHARMA EUROPE B.V.	GR
Alvesco 80 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/001	79939/20/14-1-2021	COVIS PHARMA EUROPE B.V.	GR
CICLESONIDE/GENETIC 160 μ?????αμ???a a?? ?e?asμ?, d????μα ??a e?sp??? ?p? p?es?	AT/H/1266/002	328820201	GENETIC SPA	GR
CICLESONIDE/GENETIC 320 μ?????αμ???a a?? ?e?asμ?, d????μα ??a e?sp??? ?p? p?es?	AT/H/1266/003	328820101	GENETIC SPA	GR
CICLESONIDE/GENETIC 80 μικρογραμμάρια ανά ψεκασμό, διάλυμα για	AT/H/1266/001	328820301	GENETIC SPA	GR

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εισπνοή υπό πίεση				
Airclesio 160 mikrograma stlačeni inhalat, otopina	NL/H/5651/002	HR-H-574531832	SANDOZ D.O.O.	HR
Alvesco 160 mikrograma stlačeni inhalat, otopina	not available	HR-H-058422961	COVIS PHARMA EUROPE B.V.	HR
Alvesco 80 mikrograma stlačeni inhalat, otopina	not available	HR-H-764625631	COVIS PHARMA EUROPE B.V.	HR
Alvesco 160 mikrogramm túlnyomásos inhalációs oldat	SE/H/1861/002	OGYI-T-9973/01	COVIS PHARMA EUROPE B.V.	HU
Alvesco 160 mikrogramm túlnyomásos inhalációs oldat	SE/H/1861/002	OGYI-T 9973/02	COVIS PHARMA EUROPE B.V.	HU
Alvesco 80 mikrogramm túlnyomásos inhalációs oldat	SE/H/1861/001	OGYI-T-9973/05	COVIS PHARMA EUROPE B.V.	HU
Alvesco 80 mikrogramm túlnyomásos inhalációs oldat	SE/H/1861/001	OGYI-T-9973/06	COVIS PHARMA EUROPE B.V.	HU
Ciclesonid Sandoz 160 mikrogramm túlnyomásos inhalációs oldat	NL/H/5651/002	OGYI-T-24324/01	SANDOZ HUNGÁRIA KFT	HU
Alvesco 160 micrograms pressurised inhalation, solution	SE/H/1861/002	PA22986/001/002	COVIS PHARMA EUROPE B.V.	IE
Alvesco 80 micrograms pressurised inhalation, solution	SE/H/1861/001	PA22986/001/001	COVIS PHARMA EUROPE B.V.	IE
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/002	038873117	COVIS PHARMA EUROPE B.V.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/002	038873055	COVIS PHARMA EUROPE B.V.	IT
Alvesco 160 mcg	SE/H/1861/002	038873067	COVIS PHARMA EUROPE	IT

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soluzione pressurizzata per inalazione			B.V.	
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/002	038873129	COVIS PHARMA EUROPE B.V.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/002	038873079	COVIS PHARMA EUROPE B.V.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/002	038873081	COVIS PHARMA EUROPE B.V.	IT
Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/001	038873105	COVIS PHARMA EUROPE B.V.	IT
Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/001	038873030	COVIS PHARMA EUROPE B.V.	IT
Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/001	038873042	COVIS PHARMA EUROPE B.V.	IT
Ciclesonide Genetic 160 microgrammi per erogazione, soluzione pressurizzata per inalazione	AT/H/1266/002	050839024	GENETIC SPA	IT
Ciclesonide Genetic 320 microgrammi per erogazione, soluzione pressurizzata per inalazione	AT/H/1266/003	050839036	GENETIC SPA	IT
Ciclesonide Genetic 80 microgrammi per erogazione, soluzione pressurizzata per inalazione	AT/H/1266/001	050839012	GENETIC SPA	IT
Alvesco 160 mikrogrami aerosols inhalācijām, zem spiediena, šķīdums	SE/H/1861/002	05-0019	COVIS PHARMA EUROPE B.V.	LV
Alvesco 80 mikrogrami	SE/H/1861/001	05-0018	COVIS PHARMA EUROPE	LV

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aerosols inhalācijām, zem spiediena, šķīdums			B.V.	
Alvesco 160 Inhalator, aërosol, oplossing 160 microgram/dosis	SE/H/1861/002	RVG 31633	COVIS PHARMA EUROPE B.V.	NL
Alvesco 80 Inhalator, aerosol, oplossing 80 microgram/dosis	SE/H/1861/001	RVG 31632	COVIS PHARMA EUROPE B.V.	NL
Ciclesonide ACE 160 microgram/dosis, aërosol, oplossing	AT/H/1266/001	RVG 129122	ACE PHARMACEUTICALS BV	NL
Ciclesonide ACE 320 microgram/dosis, aërosol, oplossing	AT/H/1266/001	RVG 129123	ACE PHARMACEUTICALS BV	NL
Ciclesonide ACE 80 microgram/dosis, aërosol, oplossing	AT/H/1266/001	RVG 129120	ACE PHARMACEUTICALS BV	NL
Ciclesonide Sandoz 160 microgram/dosis, aërosol, oplossing	NL/H/5651/002	RVG 130308	SANDOZ B.V.	NL
Ciclesonide Sandoz 80 microgram/dosis, aërosol, oplossing	NL/H/5651/001	RVG 130307	SANDOZ B.V.	NL
Alvesco® 160 mikrogram/dose inhalasjonsaerosol, oppløsning	SE/H/1861/002	04-2872	COVIS PHARMA EUROPE B.V.	NO
Alvesco® 80 mikrogram/dose inhalasjonsaerosol, oppløsning	SE/H/1861/001	04-2871	COVIS PHARMA EUROPE B.V.	NO
Ciclesonide Sandoz	NL/H/5651/001	22-14906	SANDOZ A/S	NO
Ciclesonide Sandoz	NL/H/5651/002	22-14905	SANDOZ A/S	NO
Alvesco 160, 160 µg/dawkę inhalacyjną; aerosol inhalacyjny, roztwór	UK/H/0699/003	11231	COVIS PHARMA EUROPE B.V.	PL
Alvesco 80, 80 µg/dawke inhalacyjna; aerosol	UK/H/0699/002	11230	COVIS PHARMA EUROPE B.V.	PL

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inhalacyjny, roztwór				
Cyxodil, 160 mikrogramów/dawkę inhalacyjną, aerozol inhalacyjny, roztwór	AT/H/1267/002	28260	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	PL
Cyxodil, 320 mikrogramów/dawkę inhalacyjną, aerozol inhalacyjny, roztwór	AT/H/1267/003	28261	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	PL
Cyxodil, 80 mikrogramów/dawkę inhalacyjną, aerozol inhalacyjny, roztwór	AT/H/1267/001	28259	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	PL
ALVESCO 160 INHALER 160 micrograme/doză soluție de inhalat presurizată	not available	9031/2016/01	COVIS PHARMA EUROPE B.V.	RO
ALVESCO 160 INHALER 160 micrograme/doză soluție de inhalat presurizată	not available	9031/2016/02	COVIS PHARMA EUROPE B.V.	RO
ALVESCO 160 INHALER 160 micrograme/doză soluție de inhalat presurizată	not available	9031/2016/03	COVIS PHARMA EUROPE B.V.	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/01	COVIS PHARMA EUROPE B.V.	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/02	COVIS PHARMA EUROPE B.V.	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/03	COVIS PHARMA EUROPE B.V.	RO
Alvesco 160 mikrogram/dos	SE/H/1861/002	21425	COVIS PHARMA EUROPE B.V.	SE

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inhalationsspray, lösning				
Alvesco 80 mikrogram/dos inhalationsspray, lösning	SE/H/1861/001	21424	COVIS PHARMA EUROPE B.V.	SE
Ciclesonide Sandoz 160 mikrogram/dos inhalationsspray, lösning	NL/H/5651/002	63699	SANDOZ A/S	SE
Ciclesonide Sandoz 80 mikrogram/dos inhalationsspray, lösning	NL/H/5651/001	63698	SANDOZ A/S	SE
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/007	COVIS PHARMA EUROPE B.V.	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/008	COVIS PHARMA EUROPE B.V.	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/009	COVIS PHARMA EUROPE B.V.	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/010	COVIS PHARMA EUROPE B.V.	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/011	COVIS PHARMA EUROPE B.V.	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/002	H/04/00155/012	COVIS PHARMA EUROPE B.V.	SI
Alvesco 80 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/001	H/04/00155/004	COVIS PHARMA EUROPE B.V.	SI
Alvesco 80	SE/H/1861/001	H/04/00155/005	COVIS PHARMA EUROPE	SI

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mikrogramov/odmerek inhalacijska raztopina pod tlakom			B.V.	
Alvesco 80 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/001	H/04/00155/006	COVIS PHARMA EUROPE B.V.	SI
AIRCLESIO 160 mikrogramov/dávka	NL/H/5651/002	14/0050/24-S	SANDOZ PHARMACEUTICALS D.D.	SK
Alvesco 160 Inhalátor	SE/H/1861/002	14/0003/05-S	COVIS PHARMA EUROPE B.V.	SK
Alvesco 80 Inhalátor	SE/H/1861/001	14/0002/05-S	COVIS PHARMA EUROPE B.V.	SK
Alvesco® 160 Inhaler	SE/H/1861/002	PL 53266/0006	COVIS PHARMA EUROPE B.V.	XI
Alvesco® 80 Inhaler	SE/H/1861/001	PL 53266/0005	COVIS PHARMA EUROPE B.V.	XI