



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 April 2019  
EMA/224952/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: ciclesonide

Procedure no.: PSUSA/00000742/201808

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<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Alvesco 80 mikrograma stlačeni inhalat, otopina	not available	HR-H-764625631	ASTRAZENECA D.O.O.	HR
Alvesco 160 mikrograma stlačeni inhalat, otopina	not available	HR-H-058422961	ASTRAZENECA D.O.O.	HR
ALVESCO 160 INHALER 160 micrograme/doză soluție de inhalat presurizată	not available	9031/2016/01	ASTRAZENECA AB	RO
ALVESCO 160 INHALER 160 micrograme/doză soluție de inhalat presurizată	not available	9031/2016/03	ASTRAZENECA AB	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/03	ASTRAZENECA AB	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/01	ASTRAZENECA AB	RO
ALVESCO 80 INHALER 80 micrograme/doză, soluție de inhalat presurizată	not available	9030/2016/02	ASTRAZENECA AB	RO
ALVESCO 160 INHALER 160 micrograme/doza solutie de inhalat presurizata	not available	9031/2016/02	ASTRAZENECA AB	RO

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Alvesco® 80 Mikrogramm Druckgasinhalation, Lösung	SE/H/1861/01	60978.01.00	ASTRAZENECA GMBH	DE
Alvesco 160 Mikrogramm Druckgasinhalation, Lösung	SE/H/1861/02	60978.02.00	ASTRAZENECA GMBH	DE
Alvesco 80 Mikrogramm - Dosieraerosol	SE/H/1861/01	1-27507	ASTRAZENECA OSTERREICH GMBH	AT
Alvesco 160 Mikrogramm - Dosieraerosol	SE/H/1861/02	1-27508	ASTRAZENECA OSTERREICH GMBH	AT
Alvesco 80 mikrogramm tálmeghnyomószó inhalációs oldat	SE/H/1861/01	OGYI-T-9973/06	ASTRAZENECA KFT.	HU
Alvesco 160 mikrogramm tálmeghnyomószó inhalációs oldat	SE/H/1861/02	OGYI-T 9973/02	ASTRAZENECA KFT.	HU
Alvesco 160 mikrogramm tálmeghnyomószó inhalációs oldat	SE/H/1861/02	OGYI-T-9973/01	ASTRAZENECA KFT.	HU
Alvesco 80 mikrogramm tálmeghnyomószó inhalációs oldat	SE/H/1861/01	OGYI-T-9973/05	ASTRAZENECA KFT.	HU
Alvesco 80 Inhalátor 80 mg/1 dózsa inhalációs roztok v tlakovom obale	SE/H/1861/01	14/0002/05-S	ASTRAZENECA AB	SK

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Alvesco 160 Inhalátor 160 µg/1 dávka inhalačný roztok v tlakovom obale	SE/H/1861/02	14/0003/05-S	ASTRAZENECA AB	SK
Alvesco, inhalationsspray, opløsning 160 mikrogram/dosis	SE/H/1861/02	37078	ASTRAZENECA A/S	DK
Alvesco, inhalationsspray, opløsning 80 mikrogram/dosis	SE/H/1861/01	37077	ASTRAZENECA A/S	DK
Alvesco 160 Inhaler	SE/H/1861/02	PL 17901/0298	ASTRAZENECA UK LIMITED	UK
Alvesco 80 Inhaler	SE/H/1861/01	PL 17901/0297	ASTRAZENECA UK LIMITED	UK
Alvesco 160 Inhaler	SE/H/1861/02	PA 0970/064/002	ASTRAZENECA UK LIMITED	IE
Alvesco 80 Inhaler	SE/H/1861/01	PA 0970/064/001	ASTRAZENECA UK LIMITED	IE
Alvesco 160 microgramos/inhalación solución para inhalación en envase a presión	SE/H/1861/02	70372	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES
Alvesco 160 Inhaler Roztok k inhalaci v tlakovém obalu	SE/H/1861/02	14/003/05-C	ASTRAZENECA AB	CZ

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Alvesco 160 mikrogram/dos inhalationsspray, lösning	SE/H/1861/02	21425	ASTRAZENECA AB	SE
Alvesco 80 mikrogram/dos inhalationsspray, lösning	SE/H/1861/01	21424	ASTRAZENECA AB	SE
ALVESCO 160 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/02	NL 34301	ASTRAZENECA S.A.S.	FR
ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/01	NL 34300	ASTRAZENECA S.A.S.	FR
Alvesco® 160 mikrogram/dose inhalasjonsaerosol, oppløsning	SE/H/1861/02	04-2872	ASTRAZENECA AS	NO
ALVESCO 160 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/02	NL 34301	ASTRAZENECA S.A.S.	FR
ALVESCO 160 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/02	NL 34301	ASTRAZENECA S.A.S.	FR

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ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/01	NL 34300	ASTRAZENECA S.A.S.	FR
ALVESCO 80 microgrammes/dose, solution pour inhalation en flacon pressuris	SE/H/1861/01	NL 34300	ASTRAZENECA S.A.S.	FR
Alvesco® 80 mikrogram/dose inhalasjonsaerosol, oppløsning	SE/H/1861/01	04-2871	ASTRAZENECA AS	NO
Alvesco 160 mikrogrami aerosols inhalācijām, zem spiediena, šķīdums	SE/H/1861/002	05-0019	ASTRAZENECA AB	LV
Alvesco 80 mikrogrami aerosols inhalācijām, zem spiediena, šķīdums	SE/H/1861/001	05-0018	ASTRAZENECA AB	LV
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/007	ASTRAZENECA AB	SI
Alvesco 80 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/01	H/04/00155/006	ASTRAZENECA AB	SI

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Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/009	ASTRAZENECA AB	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/011	ASTRAZENECA AB	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/008	ASTRAZENECA AB	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/012	ASTRAZENECA AB	SI
Alvesco 80 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/01	H/04/00155/004	ASTRAZENECA AB	SI
Alvesco 80 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/01	H/04/00155/005	ASTRAZENECA AB	SI
Alvesco 160 mikrogramov/odmerek inhalacijska raztopina pod tlakom	SE/H/1861/02	H/04/00155/010	ASTRAZENECA AB	SI

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Alvesco 160 mikrog/annos inhalaatiosumute, liuos	SE/H/1861/02	19859	ASTRAZENECA OY	FI
Alvesco 80 mikrog/annos inhalaatiosumute, liuos	SE/H/1861/01	19858	ASTRAZENECA OY	FI
Alvesco 160 mikrog/dos inhalationsspray, lösning	SE/H/1861/02	19859	ASTRAZENECA OY	FI
Alvesco 80 mikrog/dos inhalationsspray, lösning	SE/H/1861/01	19858	ASTRAZENECA OY	FI
Alvesco 160, 160 µg/dawkę inhalacyjną; aerozol inhalacyjny, roztwór	SE/H/1861/02	11231	ASTRAZENECA AB	PL
Alvesco 80, 80 µg/dawkę inhalacyjną; aerozol inhalacyjny, roztwór	SE/H/1861/01	11230	ASTRAZENECA AB	PL
Alvesco 160 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/02	20456	ASTRAZENECA AB	CY
Alvesco 80 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/01	20455	ASTRAZENECA AB	CY
Алвеско 160 микрограма, разтвор под налягане за инхалации	SE/H/1861/02	20080173	ASTRAZENECA AB	BG



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Алвеско 80 микрограма, разтвор под налягане за инхалации.	SE/H/1861/01	20080172	ASTRAZENECA AB	BG
Alvesco 160 Inhalator, aërosol, oplossing 160 microgram/dosis	SE/H/1861/02	RVG 31633	ASTRAZENECA BV	NL
Alvesco 80 Inhalator, aërosol, oplossing 80 microgram/dosis	SE/H/1861/01	RVG 31632	ASTRAZENECA BV	NL
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873117	SIMESA S.P.A.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873055	SIMESA S.P.A.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873081	SIMESA S.P.A.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873079	SIMESA S.P.A.	IT
Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/01	038873030	SIMESA S.P.A.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873067	SIMESA S.P.A.	IT

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Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/01	038873042	SIMESA S.P.A.	IT
Alvesco 160 mcg soluzione pressurizzata per inalazione	SE/H/1861/02	038873129	SIMESA S.P.A.	IT
Alvesco 80 mcg soluzione pressurizzata per inalazione	SE/H/1861/01	038873105	SIMESA S.P.A.	IT
Alvesco 160 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/002	36496/12-06-2017	ASTRAZENECA S.A	GR
Alvesco 80 μικρογραμμάρια, διάλυμα για εισπνοή υπό πίεση	SE/H/1861/001	27177/12-06-2017	ASTRAZENECA S.A	GR