



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 September 2017  
EMA/580096/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: terbutaline

Procedure no.: PSUSA/00002897/201612



<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>
Aerodur® Turbohaler® 0,5 mg, Pulver zur Inhalation	not available	13662.00.00	ASTRAZENECA GMBH	DE
Bricanyl 0,3 mg/ml mixtúra, lausn	not available	772081	ASTRAZENECA A/S	IS
Bricanyl 0,5 mg - Ampullen	not available	16.126	ASTRAZENECA OSTERREICH GMBH	AT
Bricanyl 0,5 mg/ml	not available	14/143/72-C	ASTRAZENECA UK LIMITED	CZ
Bricanyl 0,5 mg/ml injeksjonsvæske, oppløsning	not available	5617	ASTRAZENECA AS	NO
Bricanyl 0,5 mg/ml oldatos injekció	not available	OGYI-T-4167/02	ASTRAZENECA KFT.	HU
Bricanyl 0,5 mg/ml stungulyf, lausn	not available	711394 (IS)	ASTRAZENECA A/S	IS
Bricanyl 0.3 mg/ml Syrup	not available	PL 17901/0111	ASTRAZENECA UK LIMITED	UK
Bricanyl 2,5 mg/ml inhalasjonsvæske til nebulisator, oppløsning	not available	6769	ASTRAZENECA AS	NO
Bricanyl 250 Turbohaler, inhalatiepoeder 250 microgram/dosis	not available	RVG 15959	ASTRAZENECA BV	NL

<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>
Bricanyl 5 mg tabletter	not available	5618	ASTRAZENECA AS	NO
Bricanyl 5 mg tabletter	not available	8491	ASTRAZENECA AB	SE
Bricanyl 500 mcg/erogazione polvere per inalazione	not available	AIC.023471030	ASTRAZENECA S.P.A.	IT
Bricanyl 500 micrograms/ml solution for injection or infusion	not available	PA 970/36/2	ASTRAZENECA UK LIMITED	IE
Bricanyl 500 Turbuhaler, inhalatiepoeder 500 microgram/dosis	not available	RVG 12480	ASTRAZENECA BV	NL
Bricanyl Depot 5 mg depottabletter	not available	10017	ASTRAZENECA AB	SE
Bricanyl Depot 7,5 mg depottabletter	not available	9846	ASTRAZENECA AB	SE
Bricanyl Depot 7,5 mg depottabletter.	not available	6791	ASTRAZENECA AS	NO
BRICANYL L.P. 5 mg, comprimé à libération prolongée	not available	NL 15 335	ASTRAZENECA S.A.S.	FR

<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>
Bricanyl Retard 5 mg forðatöflur	not available	843549	ASTRAZENECA A/S	IS
Bricanyl Retard 7,5 mg forðatöflur	not available	833178 (IS)	ASTRAZENECA A/S	IS
Bricanyl Retard, depottabletter	not available	10954	ASTRAZENECA A/S	DK
BRICANYL RETARD, DEPOTTABLETTER	not available	10555	ASTRAZENECA A/S	DK
Bricanyl Turbohaler 0,5 mg pro Dosis Pulver zur Inhalation	not available	1-19028	ASTRAZENECA OSTERREICH GMBH	AT
Bricanyl Turbohaler, 500 microgramas/dose, pó para inalação	not available	8525220	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Bricanyl Turbohaler, 500 microgramas/dose, pó para inalação	not available	5391479	ASTRAZENECA PRODUTOS FARMACEUTICOS LDA.	PT
Bricanyl Turbuhaler 0,25 mg/skammt innöndunarduft	not available	920079 (IS)	ASTRAZENECA A/S	IS
Bricanyl Turbuhaler 0,25mg/dose inhalasjonspulver	not available	7746	ASTRAZENECA AS	NO

<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>
Bricanyl Turbuhaler 0,5 mg/skammt innöndunarduft	not available	870025	ASTRAZENECA A/S	IS
Bricanyl Turbuhaler 0,5mg/dose inhalasjonspulver	not available	7273	ASTRAZENECA AS	NO
Bricanyl Turbuhaler, 0,25 mg/dos inhalationspulver.	not available	11495	ASTRAZENECA AB	SE
Bricanyl Turbuhaler, 0,5 mg/dos inhalationspulver	not available	10570	ASTRAZENECA AB	SE
Bricanyl Turbuhaler, inhalationspulver	not available	12829	ASTRAZENECA A/S	DK
Bricanyl Turbuhaler, inhalationspulver	not available	14925	ASTRAZENECA A/S	DK
Bricanyl, 0,5 mg/ml, injektionsvätska/koncentrat till infusionsvätska, lösning	not available	8489	ASTRAZENECA AB	SE
Bricanyl, 2,5 mg/ml lösning för nebulisator, endosbehållare	not available	9655	ASTRAZENECA AB	SE
Bricanyl, inhalationsvæske til nebulisator, opløsning	not available	10603	ASTRAZENECA A/S	DK

<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>
Bricanyl, injektionsvæske, opløsning	not available	5600	ASTRAZENECA A/S	DK
Bricanyl, injektionsvæske, opløsning	not available	10479	ASTRAZENECA A/S	DK
Bricanyl, oral opløsning	not available	6029	ASTRAZENECA A/S	DK
Bricanyl® 0,5 mg Injektionslösung	not available	6084327.00.00	ASTRAZENECA GMBH	DE
BRICANYL® 0,5 mg/1 ml, solution injectable en ampoule	not available	NL 9094	ASTRAZENECA S.A.S.	FR
BRICANYL® 5 mg/2 ml, solution pour inhalation par nébuliseur en récipient unidose	not available	NL 17 702	ASTRAZENECA S.A.S.	FR
Bricanyl® Injection, 0.5 mg/ml, solution for injection or infusion	not available	PL 17901/0112	ASTRAZENECA UK LIMITED	UK
Bricanyl® Respules® 2.5 mg/ml Nebuliser Solution	not available	PL 17901/0114	ASTRAZENECA UK LIMITED	UK
Bricanyl® Tablets 5mg	not available	PL 17901/0116	ASTRAZENECA UK LIMITED	UK

<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>
Bricanyl® Turbohaler® 500 micrograms per metered dose, inhalation powder	not available	PA 970/36/8	ASTRAZENECA UK LIMITED	IE
Bricanyl® Turbohaler®, 0.5mg/dose, inhalation powder	not available	PL 17901/0117	ASTRAZENECA UK LIMITED	UK
Bricanyl® Turbuhaler® 0,25 mg/annos inhalaatiojauheet	not available	10913	ASTRAZENECA OY	FI
Bricanyl® Turbuhaler® 0,5 mg/annos inhalaatiojauheet	not available	9960	ASTRAZENECA OY	FI
BRICANYL® TURBUHALER® 500 microgrammes/dose, poudre pour inhalation	not available	NL 16 580	ASTRAZENECA S.A.S.	FR
Bricanyl-Duriles® 7,5 mg, Retardtabletten	not available	607.00.00	ASTRAZENECA GMBH	DE
TERBASMIN® TURBUHALER® 500 microgramos polvo para inhalación	not available	58.859	ASTRAZENECA FARMACÉUTICA SPAIN, S.A.	ES