



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 September 2018  
EMA/619619/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: haemophilus influenzae / klebsiella ozaenae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes / streptococcus viridans vaccine

Procedure no.: PSUSA/00001582/201712



<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>
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609026	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609014	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609026	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609014	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609026	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Adulti 7 mg capsule rigide	not available	026609014	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609040	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609038	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609040	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609038	ABIOGEN PHARMA S.P.A.	IT

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BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609040	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg capsule rigide	not available	026609038	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg granulato per sospensione orale	not available	026609053	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg granulato per sospensione orale	not available	026609065	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg granulato per sospensione orale	not available	026609053	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg granulato per sospensione orale	not available	026609065	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg granulato per sospensione orale	not available	026609053	ABIOGEN PHARMA S.P.A.	IT
BRONCHO MUNAL Bambini 3,5 mg	not available	026609065	ABIOGEN PHARMA S.P.A.	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
granulato per sospensione orale				
Broncho Vaxom Adultes	not available	BE137322	OM PHARMA S.A.	BE
BRONCHO VAXOM Adulti 7 mg capsule rigide	not available	026029013	OM PHARMA S.A.	IT
BRONCHO VAXOM Bambini 3,5 mg capsule rigide	not available	026029088	OM PHARMA S.A.	IT
BRONCHO VAXOM Bambini 3,5 mg capsule rigide	not available	026029037	OM PHARMA S.A.	IT
BRONCHO VAXOM Bambini 3,5 mg granulato in bustina	not available	026029090	OM PHARMA S.A.	IT
Broncho-Munal Erwachsene 7 mg Hartkapseln	not available	185A/89	OM PHARMA S.A.	DE
Broncho-Munal Kinder 3,5 mg Hartkapseln	not available	184A/89	OM PHARMA S.A.	DE
Broncho-Vaxom 20mg καψάκιο σκληρό	not available	26879/23-3-2016	GAP S.A.	GR

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
Broncho-Vaxom 3,5 mg granulado	not available	8529263	OM PHARMA S.A.	PT
Broncho-Vaxom 3,5 mg- Kapseln für Kinder	not available	2-00002	OM PHARMA S.A.	AT
Broncho-Vaxom 40mg καψάκιο σκληρό	not available	26877/23-3-2016	GAP S.A.	GR
Broncho-Vaxom 7 mg- Kapseln für Erwachsene	not available	2-00001	OM PHARMA S.A.	AT
BRONCHO-VAXOM ADULȚI, capsule 7 mg	not available	5733/2013/02	OM PHARMA S.A.	RO
BRONCHO-VAXOM ADULȚI, capsule 7 mg	not available	5733/2013/01	OM PHARMA S.A.	RO
Broncho-Vaxom adulto 7mg cápsula	not available	9529230	OM PHARMA S.A.	PT
Broncho-Vaxom adulto 7mg cápsula	not available	5366505	OM PHARMA S.A.	PT
BRONCHO-VAXOM COPII, 3,5 mg pulbere pentru suspensie orală	not available	7822/2015/01	OM PHARMA S.A.	RO

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BRONCHO-VAXOM COPII, capsule 3,5 mg	not available	5732/2013/02	OM PHARMA S.A.	RO
BRONCHO-VAXOM COPII, capsule 3,5 mg	not available	5732/2013/01	OM PHARMA S.A.	RO
Broncho-Vaxom dla dzieci, 3,5 mg, granulát w saszetkach	not available	17048	OM PHARMA S.A.	PL
Broncho-Vaxom Enfants	not available	BE137313	OM PHARMA S.A.	BE
Broncho-Vaxom Infantil, 3,5 mg cápsulas, duras	not available	9529214	OM PHARMA S.A.	PT
Broncho-Vaxom OM kemény kapszula felnotteknek	not available	OGYI-T-9751/01	OM PHARMA S.A.	HU
BRONCHO-VAXOM OM kemény kapszula gyermekeknek	not available	OGYI-T-9752/01	OM PHARMA S.A.	HU
BRONCHO-VAXOM por belsőleges oldathoz gyermekeknek	not available	OGYI-T-10309/01	OM PHARMA S.A.	HU
BRONCHO-VAXOM por belsőleges oldathoz gyermekeknek	not available	OGYI-T-10309/02	OM PHARMA S.A.	HU

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BRONCHO-VAXOM pre deti, 3,5 mg perorálny prášok	not available	59/0507/06S	OM PHARMA S.A.	SK
BRONCHO-VAXOM pre deti, 3,5 mg tvrdé kapsuly	not available	59/0052/84S	OM PHARMA S.A.	SK
Broncho-Vaxom pro adultis, 7 mg, tvrdé tobolky	not available	59/053/84-S/C	OM PHARMA S.A.	CZ
Broncho-Vaxom pro infantibus sáčky	not available	59/216/06-C	OM PHARMA S.A.	CZ
Broncho-Vaxom pro infantibus, 3,5 mg, tvrdé tobolky	not available	59/052/84-S/C	OM PHARMA S.A.	CZ
Broncho-Vaxom, 3,5 mg, kapsulki, twarde	not available	R/0438	OM PHARMA S.A.	PL
Broncho-Vaxom, 7 mg, kapsulki, twarde	not available	R/0629	OM PHARMA S.A.	PL
BRONCHO-VAXOM® Erwachsene, 7 mg, Kapseln	not available	35A/83	OM PHARMA S.A.	DE
BRONCHO-VAXOM® Kinder, 3,5 mg, Kapseln	not available	34A/83	OM PHARMA S.A.	DE

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BRONCHO-VAXOM® pre dospelych	not available	59/0053/84-S	OM PHARMA S.A.	SK
IMMUBRON "50 mg compresse sublinguali"	not available	026422028	BRUSCHETTINI S.R.L	IT
ISMIGEN 50 mg compresse sublinguali	not available	026224016	LALLEMAND PHARMA EUROPE	IT
ISMIGEN tabletki podjezykowe	not available	15581	LALLEMAND PHARMA EUROPE	PL
PIR-05 7mg υπογλώσσια δισκία	not available	67229	RAFARM SA.	GR
PROVAX	not available	2318186	ALMIRALL PRODUTOS FARMACÊUTICOS, LDA.	PT
БРОНХО – ВАККОМ за възрастни 7 mg твърди капсули	not available	20030171	OM PHARMA S.A.	BG
БРОНХО – ВАККОМ ЗА ДЕЦА 3,5 mg гранули	not available	20050073	OM PHARMA S.A.	BG
Бронхо–Ваксом за деца 3,5 mg твърди капсули	not available	20030170	OM PHARMA S.A.	BG