



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 December 2021  
EMA/689851/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: bacterial lysate of haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus mitis / streptococcus pneumoniae / streptococcus pyogenes, bacterial lysate of haemophilus influenzae / klebsiella pneumoniae / moraxella catarrhalis / staphylococcus aureus / streptococcus pneumoniae / streptococcus pyogenes, streptococcus pneumoniae / streptococcus aga

Procedure no.: PSUSA/00002786/202103



<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>
Buccalin® Filmtabletten Wirkstoffe: Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus sp., Staphylococcus aureus	not available	1-23470	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	AT
Luivac Tabletten	not available	1-23378	DAIICHI SANKYO AUSTRIA GMBH	AT
Luivac Tableta	not available	59/381/95-C	DAIICHI SANKYO EUROPE GMBH	CZ
Luivac® 3 mg Tabletten	not available	75A/91	DAIICHI SANKYO EUROPE GMBH	DE
LANTIGEN B gocce orali, sospensione 1 flacone da 18 ml.	not available	025709015	BRUSCHETTINI S.R.L.	IT
Buccalin Adulti compresse gastroresistenti Bambini compresse gastroresistenti	not available	022928016	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Buccalin Adulti compresse gastroresistenti Bambini compresse gastroresistenti	not available	022928028	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
PASPAT 3 MG COMPRESSE	not available	028790018	DAIICHI SANKYO ITALIA S.P.A	IT

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Luivac 3 mg tabletes	not available	LT/1/98/3530/001	DAIICHI SANKYO EUROPE GMBH	LT
Luivac 3 mg tabletes Baktēriju lizāti	not available	00-0008	DAIICHI SANKYO EUROPE GMBH	LV
LANTIGEN B oral drops, suspension, 1 bottle of 18 ml	not available	MA016/00101	BRUSCHETTINI S.R.L	MT
PASPAT® Oral	not available	2528081	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
PASPAT® Oral	not available	2528180	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Luivac 3 mg comprimidos	not available	2902484	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Luivac 3 mg comprimidos	not available	2902583	DAIICHI SANKYO PORTUGAL, UNIP. LDA	PT
Lantigen B Suspensão oral	not available	8525006	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Lantigen B Suspensão oral	not available	8525014	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT

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Lantigen B Suspensão oral	not available	8525022	LABORATÓRIO MEDINFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Luivac 3 mg comprimato	not available	4595/2012/01	ALVOGEN MALTA OPERATIONS (ROW) LTD	RO
Luivac 3 mg comprimato	not available	4595/2012/02	ALVOGEN MALTA OPERATIONS (ROW) LTD	RO
Lantigen B, picaturi orale suspensie	not available	1473/2009/01	BRUSCHETTINI S.R.L	RO
Luivac 3 mg, tableta	not available	59/0104/96-S	DAIICHI SANKYO EUROPE GMBH	SK