

Annex I

List of nationally authorised medicinal products

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Daiichi Sankyo Austria GmbH	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Austria	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1 Giga Units Tablet, Haemophilus Influenzae 1.5 Giga Units Tablet, Staphylococcus Aureus 1 Giga Units Tablet, Streptococcus Pneumoniae 1 Giga Units Tablet	Film-Coated Tablet	Oral Use
Austria	Om Pharma S.A.	Broncho-Vaxom Für Erwachsene	Freeze-Dried (Lyophilised), Standardised Bacterial Lysate 7mg Capsule	Capsule, Hard	Oral Use
Austria	Om Pharma S.A.	Broncho-Vaxom Für Kinder	Freeze-Dried (Lyophilised), Standardised Bacterial Lysate 3.5mg Capsule	Capsule, Hard	Oral Use
Belgium	Om Pharma S.A.	Broncho Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Belgium	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Bb - Ncipd Ltd.	Respivax	Haemophilus Influenzae Type B (Hib) 0.625 Giga Cells / 25mg, Branhamella Catarrhalis Lysate 0.625 Giga Cells / 25mg, Klebsiella Pneumoniae (Inactivated) 0.625 Giga Cells / 25mg, Staphylococcus Aureus Inactivated Bacteria 0.625 Giga Cells / 25mg, Streptococcus Pneumoniae Inactivated Bacteria 0.625 Giga Cells / 25mg, Streptococcus Pyogenes Inactivated Bacteria 0.625 Giga Cells / 25mg	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Bulgaria	Bb - Ncipd Ltd.	Respivax	Haemophilus Influenzae Type B (Hib) 1.25 Giga Cells / 50mg, Branhamella Catarrhalis Lysate 1.25 Giga Cells / 50mg, Klebsiella Pneumoniae (Inactivated) 1.25 Giga Cells / 50mg, Staphylococcus Aureus Inactivated Bacteria 1.25 Giga Cells / 50mg, Streptococcus Pneumoniae Inactivated Bacteria 1.25 Giga Cells / 50mg, Streptococcus Pyogenes Inactivated Bacteria 1.25 Giga Cells / 50mg	Tablet	Oral Use
Bulgaria	Om Pharma S.A.	Бронхо – Ваксом За Възрастни	Standardized Lyophilisate Of Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Om Pharma S.A.	Бронхо – Ваксом За Деца	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules	Oral Use
Bulgaria	Om Pharma S.A.	Бронхо–ваксом За Деца	Standardized Lyophilisate Of Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Bulgaria	Pierre Fabre Medicament	Рибомунил	Proteoglycans Of Klebsiella Pneumoniae 1.125mg Sachet, Ribosomal Fractions (Ribosomes With A Titre Of 70% Rna) 0.75mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use
Czech Republic	Daiichi Sankyo Europe Gmbh	Luivac	Lysatum Bacteriale Mixtum 3mg Tablet	Tablet	Oral Use
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Adultis	Lysatum Bacteriale Mixtum 7mg Capsule	Capsule, Hard	Oral Use
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Infantibus	Lysatum Bacteriale Mixtum 3.5mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Om Pharma S.A.	Broncho-Vaxom Pro Infantibus	Lysatum Bacteriale Mixtum 3.5mg Sachet	Granules In Sachet	Oral Use
Czech Republic	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Sachet, Ribosomes Of Haemophilus Influenzae 0.5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 3 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Sachet	Granules For Oral Solution	Oral Use
Czech Republic	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Germany	Daiichi Sankyo Europe GmbH	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Germany	Om Pharma S.A.	Broncho-Munal Erwachsene	Lyophilised, Standardised Bacterial Extract 7mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Munal Kinder	Lyophilised, Standardised Bacterial Extract 3.5mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Vaxom	Lyophilised, Standardised Bacterial Extract 3.5mg Capsule	Capsule, Hard	Oral Use
Germany	Om Pharma S.A.	Broncho-Vaxom Erwachsene	Lyophilised, Standardised Bacterial Extract 7mg Capsule	Capsule	Oral Use
Greece	Gap S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Greece	Gap S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Greece	Rafarm Sa.	Pir-05	Lyophilized Bacterial Lysates 7mg Tablet	Sublingual Tablet	Sublingual Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Hungary	Om Pharma S.A.	Broncho-Vaxom Felnotteknek	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Hungary	Om Pharma S.A.	Broncho-Vaxom Gyermekeknek	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Hungary	Om Pharma S.A.	Broncho-Vaxom Gyermekeknek	Lyophilized Bacterial Lysates 3.5mg Sachet	Powder For Oral Solution	Oral Use
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules In Sachet	Oral Use
Italy	Abiogen Pharma S.P.A.	Broncho Munal	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules For Oral Suspension	Oral Use
Italy	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Ommunal	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Bruschettini S.R.L	Immubron	Glycine 43mg Tablet, Haemophilus Influenzae Type B (Hib) 6 Giga Organisms Tablet, Klebsiella Ozaenae 6 Giga Organisms Tablet, Klebsiella Pneumoniae 6 Giga Organisms Tablet, Neisseria Catarrhalis 6 Giga Organisms Tablet, Staphylococcus Aureus 6 Giga Organisms Tablet, Streptococcus Pneumoniae 6 Giga Organisms Tablet, Streptococcus Pyogenes 6 Giga Organisms Tablet, Streptococcus Oralis 6 Giga Organisms Tablet, Lyophilized Bacterial Lysates 50mg Tablet	Sublingual Tablet	Sublingual Use
Italy	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2agu/MI, Klebsiella Pneumoniae 39.8agu/MI, Staphylococcus Aureus 79.6agu/MI, Streptococcus Pneumoniae 63.2dagu/MI, Streptococcus Pyogenes 126.2agu/MI, Moraxella Catarrhalis 39.9agu/MI	Oral Drops, Suspension	Oral Use
Italy	Daiichi Sankyo Italia S.P.A	Paspat	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Italy	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1000 Mega Units Tablet, Haemophilus Influenzae 1500 Mega Units Tablet, Staphylococcus Aureus 1000 Mega Units Tablet, Streptococcus Pneumoniae 1000 Mega Units Tablet	Gastro-Resistant Tablet	Oral Use
Italy	Laboratorio Farmaceutico S.I.T. S.R.L.	Buccalin	Streptococcus Agalactiae 1000 Mega Units Tablet, Haemophilus Influenzae 1500 Mega Units Tablet, Staphylococcus Aureus 1000 Mega Units Tablet, Streptococcus Pneumoniae 1000 Mega Units Tablet	Gastro-Resistant Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Lallemand Pharma Europe	Ismigen	Haemophilus Influenzae 6 Giga Cells Tablet, Klebsiella Ozaenae 6 Giga Cells Tablet, Klebsiella Pneumoniae 6 GigaCells Tablet, Neisseria Catarrhalis 6 Giga Cells Tablet, Staphylococcus Aureus 6 Giga Cells Tablet, Streptococcus Pneumoniae 6 Giga Cells Tablet, Streptococcus Pyogenes 6 Giga Cells Tablet, Streptococcus Oralis 6GigaCells Tablet	Sublingual Tablet	Sublingual Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules In Sachet	Oral Use
Italy	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Italy	Pierre Fabre Pharma S.R.L.	Immucytal	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Italy	Pierre Fabre Pharma S.R.L.	Immucytal	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Latvia	Daiichi Sankyo Europe GmbH	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Latvia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 3.5mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Latvia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7mg Capsule	Capsule, Hard	Oral Use
Lithuania	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Lithuania	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7mg Capsule	Capsule, Hard	Oral Use
Lithuania	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Lithuania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Lithuania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Luxembourg	Daiichi Sankyo Europe Gmbh	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Luxembourg	Om Pharma S.A.	Broncho Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Luxembourg	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Malta	Bruschettini S.R.L	Immubron	Glycine 43mg Tablet, Haemophilus Influenzae Type B (Hib) 6 Giga Organisms Tablet, Klebsiella Ozaenae 6 Giga Organisms Tablet, Klebsiella Pneumoniae 6 Giga Organisms Tablet, Neisseria Catarrhalis 6 Giga Organisms Tablet, Staphylococcus Aureus 6 Giga Organisms Tablet, Streptococcus Pneumoniae 6 Giga Organisms Tablet, Streptococcus Pyogenes 6 Giga Organisms Tablet, Streptococcus Viridans 6 Giga Organisms Tablet, Lyophilized Bacterial Lysates 50mg Tablet	Sublingual Tablet	Sublingual Use
Malta	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2agu/MI, Klebsiella Pneumoniae 39.8agu/MI, Staphylococcus Aureus 79.6agu/MI, Streptococcus Pneumoniae 63.2agu/MI, Streptococcus Pyogenes 126.2agu/MI, Moraxella Catarrhalis 39.9agu/MI	Oral Drops, Suspension	Oral Use
Poland	Daiichi Sankyo Europe GmbH	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Forte	Escherichia Coli (Inactivated) 200 Mega Cells / MI, Klebsiella Pneumoniae (Inactivated) 100 Mega Cells / MI, Staphylococcus Aureus Inactivated Bacteria 500 Mega Cells / MI, Staphylococcus Epidermidis Inactivated Bacteria 500 Mega Cells / MI, Streptococcus Salivarius Inactivated Bacteria 100 Mega Cells / MI, Streptococcus Pneumoniae Inactivated Bacteria 100 Mega Cells / MI, Streptococcus Pyogenes Inactivated Bacteria 100 Mega Cells / MI, Haemophilus Influenzae Inactivated Bacteria 100 Mega Cells / MI, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 200 Mega Cells / MI, Moraxella Catarrhalis Inactivated Bacteria 100 Mega Cells / MI	Suspension For Injection	Intramuscular Use \$ Subcutaneous Use
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Mite	Escherichia Coli (Inactivated) 20 Mega Cells / MI, Klebsiella Pneumoniae (Inactivated) 10 Mega Cells / MI, Staphylococcus Aureus Inactivated Bacteria 50 Mega Cells / MI, Staphylococcus Epidermidis Inactivated Bacteria 50 Mega Cells / MI, Streptococcus Salivarius Inactivated Bacteria 10 Mega Cells / MI, Streptococcus Pneumoniae Inactivated Bacteria 10 Mega Cells / MI, Streptococcus Pyogenes Inactivated Bacteria 10 Mega Cells / MI, Haemophilus Influenzae Inactivated Bacteria 10 Mega Cells / MI, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 20 Mega Cells / MI, Moraxella Catarrhalis Inactivated Bacteria 10 Mega Cells / MI	Nasal Drops, Suspension	Nasal Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Mite	Escherichia Coli (Inactivated) 20 Mega Cells / MI, Klebsiella Pneumoniae (Inactivated) 10 Mega Cells / MI, Staphylococcus Aureus Inactivated Bacteria 50 Mega Cells / MI, Staphylococcus Epidermidis Inactivated Bacteria 50 Mega Cells / MI, Streptococcus Salivarius Inactivated Bacteria 10 Mega Cells / MI, Streptococcus Pneumoniae Inactivated Bacteria 10 Mega Cells / MI, Streptococcus Pyogenes Inactivated Bacteria 10 Mega Cells / MI, Haemophilus Influenzae Inactivated Bacteria 10 Mega Cells / MI, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 20 Mega Cells / MI, Moraxella Catarrhalis Inactivated Bacteria 10 Mega Cells / MI	Suspension For Injection	Intramuscular Use \$ Subcutaneous Use
Poland	Instytut Biotechnologii Surowic I Szczepionek Biomed Spółka Akcyjna	Polyvaccinum Submite	Escherichia Coli (Inactivated) 2 Mega Cells / MI, Klebsiella Pneumoniae (Inactivated) 1 Mega Cells / MI, Staphylococcus Aureus Inactivated Bacteria 5 Mega Cells / MI, Staphylococcus Epidermidis Inactivated Bacteria 5 Mega Cells / MI, Streptococcus Salivarius Inactivated Bacteria 1 Mega Cells / MI, Streptococcus Pneumoniae Inactivated Bacteria 1 Mega Cells / MI, Streptococcus Pyogenes Inactivated Bacteria 1 Mega Cells / MI, Haemophilus Influenzae Inactivated Bacteria 1 Mega Cells / MI, Corynebacterium Pseudodiphtheriticum Inactivated Bacteria 2 Mega Cells / MI, Moraxella Catarrhalis Inactivated Bacteria 1 Mega Cells / MI	Suspension For Injection	Intramuscular Use \$ Subcutaneous Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Lallemand Pharma Europe	Ismigen	Haemophilus Influenzae 6 Giga Cells Tablet, Klebsiella Ozaenae 6 Giga Cells Tablet, Klebsiella Pneumoniae 6 Giga Cells Tablet, Neisseria Catarrhalis 6 Giga Cells Tablet, Staphylococcus Aureus 6 Giga Cells Tablet, Streptococcus Pneumoniae 6 Giga Cells Tablet, Streptococcus Pyogenes 6 Giga Cells Tablet, Streptococcus Viridans 6 Giga Cells Tablet	Sublingual Tablet	Sublingual Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules In Sachet	Oral Use
Poland	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Proteoglycans Of Klebsiella Pneumoniae 1.125mg Sachet, Ribosomal Fractions (Ribosomes With A Titre Of 70% Rna) 0.75mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Pierre Fabre Medicament Polska Sp. Z O.O.	Ribomunyl	Proteoglycanes Of Klebsiella Pneumoniae 1.125mg Sachet, Ribosomes Of Haemophilus Influenzae 5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 30 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 35 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 30 Units Sachet	Granules For Oral Solution	Oral Use
Portugal	Almirall Produtos Farmacêuticos, Lda.	Provax	Diplococcus Pneumoniae Type I 6000 Milli I.U. Tablet, Haemophilus Influenzae 6000 Milli I.U. Tablet, Klebsiella Ozaenae 6 Milli I.U. Tablet, Klebsiella Pneumoniae 6000 Milli I.U. Tablet, Neisseria Catarrhalis 6000 Milli I.U. Tablet, Staphylococcus Aureus 6000 Milli I.U. Tablet, Streptococcus Pyogenes 6000 Milli I.U. Tablet, Streptococcus Viridans 6000 Milli I.U. Tablet	Tablet	Oral Use
Portugal	Daiichi Sankyo Portugal, Unip. Lda	Paspal Oral	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Portugal	Lusomedicamenta – Sociedade Técnica Farmacêutica, Sa	Lantigen B	Haemophilus Influenzae 50.2agu/MI, Klebsiella Pneumoniae 39.8agu/MI, Staphylococcus Aureus 79.6agu/MI, Streptococcus Pneumoniae 63.2agu/MI, Streptococcus Pyogenes 126.2agu/MI, Moraxella Catarrhalis 39.9agu/MI	Oral Suspension	Sublingual Use
Portugal	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 3.5mg Sachet	Granules	Oral Use
Portugal	Om Pharma S.A.	Broncho-Vaxom	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Portugal	Om Pharma S.A.	Broncho-Vaxom Infantil,	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Pierre Fabre Medicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Portugal	Pierre Fabre Medicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Portugal	Pierre Fabre Medicament Portugal, Lda.	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Tablet	Oral Use
Romania	Alvogen Malta Operations (Row) Ltd	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use
Romania	Bruschettini S.R.L	Lantigen B	Haemophilus Influenzae Type B (Hib) 50.2agu/MI, Klebsiella Pneumoniae 39.8agu/MI, Staphylococcus Aureus 79.6agu/MI, Streptococcus Pneumoniae 63.2agu/MI, Streptococcus Pyogenes 126.2agu/MI, Moraxella Catarrhalis 39.9agu/MI	Oral Drops, Suspension	Oral Use
Romania	Daiichi Sankyo Europe GmbH	Luivac	Bacterial Lysate 3mg Tablet	Tablet	Oral Use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Romania	Om Pharma S.A.	Broncho-Vaxom Adulți	Lyophilized Bacterial Lysates 7mg Capsule	Capsule, Hard	Oral Use
Romania	Om Pharma S.A.	Broncho-Vaxom Copii	Lyophilized Bacterial Lysates 3.5mg Capsule	Capsule, Hard	Oral Use
Romania	Om Pharma S.A.	Broncho-Vaxom Copii	Lyophilized Bacterial Lysates 3.5mg Sachet	Powder For Oral Suspension	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units / MI, Ribosomes Of Haemophilus Influenzae 0.5 Units / MI, Ribosomes Of Streptococcus Pneumoniae 3 Units / MI, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units / MI, Ribosomes From Streptococcus Pyogenes Group A 3 Units / MI	Granules For Oral Solution	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units Tablet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Romania	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units, Ribosomes Of Haemophilus Influenzae 0.5 Units, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units, Ribosomes From Streptococcus Pyogenes Group A 3 Units	Granules For Oral Solution	Oral Use
Slovakia	Daiichi Sankyo Europe Gmbh	Luivac	Lysatum Bacteriale Mixtum 3mg Tablet	Tablet	Oral Use
Slovakia	Om Pharma S.A.	Broncho-Vaxom	Lysatum Bacteriale Mixtum 7mg Capsule	Capsule, Hard	Oral Use

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Slovakia	Om Pharma S.A.	Broncho-Vaxom Pre Deti	Lysatum Bacteriale Mixtum 3.5mg Capsule	Capsule, Hard	Oral Use
Slovakia	Om Pharma S.A.	Broncho-Vaxom Pre Deti	Lysatum Bacteriale Mixtum 3.5mg Sachet	Oral Powder	Oral Use
Slovakia	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Sachet, Ribosomes Of Haemophilus Influenzae 0.5 Units Sachet, Ribosomes Of Streptococcus Pneumoniae 3 Units Sachet, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Sachet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Sachet	Granules For Oral Solution	Oral Use
Slovakia	Pierre Fabre Medicament	Ribomunyl	Membranes Fractions Of Klebsiella Pneumoniae 15 Units Tablet, Ribosomes Of Haemophilus Influenzae 0.5 Units Tablet, Ribosomes Of Streptococcus Pneumoniae 3 Units, Ribosomal Fractions Of Klebsiella Pneumoniae 3.5 Units Tablet, Ribosomes From Streptococcus Pyogenes Group A 3 Units Tablet	Tablet	Oral Use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 3.5mg Capsule	Capsule, Hard	Oral Use
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Broncho-Munal	Bacterial Lysate 7mg Capsule	Capsule, Hard	Oral Use