

Final Belgian list:

(Last update 4/03/2021)

Marketing name	Active substance	MAH	Reason on list
ADAKVEO	CRIZANLIZUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New biological, conditional auth
ADCETRIS	BRENTUXIMAB VEDOTINE	TAKEDA PHARMA A/S	New AS, Conditional auth, PASS
ADYNOVI	RURIOCTOCOG ALFA PEGOL	BAXALTA INNOVATIONS GMBH	New AS, PASS, New Biological
AFLURIA TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SEQIRUS NETHERLANDS B.V.	New biological
AFSTYLA	LONOCOTOCOG ALFA	CSL BEHRING GmbH	New AS, New Biological
AIMOVIG	ERENUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
AJOVY	FREMANEZUMAB	TEVA GmbH	New AS, New Biological
ALECENSA	ALECTINIB	ROCHE REGISTRATION LIMITED	New AS, Conditional auth
ALOFISEL	DAVASTROCEL	TAKEDA PHARMA A/S	New AS, New biological
ALPHA-RIX TETRA	INFLUENZA VACCINE INACTIVATED	GLAXOSMITHKLINE BIOLOGICALS S.A.	New Biological
ALPROLIX	EFTRENOCOG ALFA	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	New AS, New Biological
ALUNBRIG	BRIGATINIB	TAKEDA PHARMA A/S	New AS
AMGEVITA	ADALIMUMAB	AMGEN EUROPE BV	New Biological
AMSPARITY	ADALIMUMAB	PFIZER EUROPE MA EEIG	New Biological
ANORO ELLIPTA	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
ATRIANCE	NELARABINE 5.00 MG/ML	GLAXO GROUP LTD	Auth under excep circumstances
AXUMIN	FUCICLOVINE	BLUE EARTH DIAGNOSTICS LTD	New AS
AYBINTIO	BEVACIZUMAB	SAMSUNG BIOEPIS NL B.V.	New biological
AYVAKYT	AVAPRITINIB	BLUEPRINT MEDICINES (NETHERLANDS) B.V.	New AS, conditional auth
BATREVAC TETRA	INFLUENZA VIRUS SURFACE ANTIGENS, INACTIVATED (HAEMAGGLUTININ AND NEURAMINIDASE)	MYLAN HEALTHCARE B.V.	New Biological
BAVENCIO	AVELUMAB	MERCK EUROPE B.V.	New AS, Conditional auth, New biological
BELLINA	CHLORMADINONE, ETHINYLESTRADIOL	GEDEON RICHTER Plc	Outcome Referral Art 31, PASS
BENLYSTA	BELIMUMAB	GLAXO GROUP LTD	New AS
BEOVU	BROLUCIZUMAB	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
BESPONSA	INOTUZUMAB OZOGAMICIN	PFIZER LIMITED	New AS, New Biological
BESREMI	ROPEGINTERFERON ALFA-2B	AOP ORPHAN PHARMACEUTICALS AG	New AS, New Biological
BIKTARVY	BICTEGRAVIR/ EMTRICITABINE/ TENOFOVIR/ ALAFENAMIDE	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS
BIOTHRAX (also known as BaciThrax in France)	ANTHRAX ANTIGEN FILTRATE	EMERGENT SALES AND MARKETING GERMANY GmbH	New Biological
BLENREP	BELANTAMAB MAFODOTIN	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS, New biological, conditional auth
BLINCYTO	BLINATUMOMAB	AMGEN EUROPE BV	New AS, Conditional auth

BLITZIMA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
BOSULIF	BOSUTINIB (MONOHYDRATE) 100.00 MG	PFIZER LIMITED	New AS, Conditional auth, PASS
BRAFTOVI	ENCORAFENIB	PIERRE FABRE MEDICAMENT	New AS
BRETARIS GENUAIR	ACLIDINIUM BROMIDE	ALMIRALL S.A	New AS, PASS
BRIMICA GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ALMIRALL S.A	New AS, PASS
BRINEURA	CERLIPONASE ALFA	BIOMARIN INTERNATIONAL LTD	New AS, Auth under excep circumstances, PASS
CABLIVI	CAPLACIZUMAB	ABLYNX N.V.	New AS, New Biological
CABOMETYX	CABOZANTINIB	IPSEN PHARMA	New AS
CALQUENCE	ACALABRUTINIB	ASTRAZENECA AB	New AS
CAPRELSA	VANDETANIB	ASTRAZENECA AB	New AS, Conditional auth
CEGFILA (previously PEGFILGRASTIM MUNDIPHARMA)	PEGFILGRASTIM	MUNDIPHARMA CORPORATION (IRELAND) LIMITED	New Biological
CEPLENE	HISTAMINE DIHYDROCHLORIDE	NOVENTIA PHARMA SRL	Auth under excep circumstances
CERDELGA	ELIGLUSTAT	GENZYME EUROPE B.V.	PASS
CHENODEOXYCHOLIC ACID SIGMA-TAU	CHENODEOXYCHOLIC ACID	SIGMA-TAU ARZNEIMITTEL GmbH	Auth under excep circumstances, PASS
CIDOFOVIR	CIDOFOVIR	EMCURE PHARMA UK LTD	PASS
CINQAERO	RESLIZUMAB	TEVA B.V.	New AS, New biological
CINRYZE	C1-INHIBITOR 500.00 IU	SHIRE SERVICES BVBA	PASS
COAGADEX	HUMAN COAGULATION FACTOR X	BIO PRODUCTS LABRATORY LTD	New Biological
COMETRIQ	CABOZANTINIB	IPSEN PHARMA	New AS, Conditional auth
COMIRNATY	COVID-19 Mrna VACCINE (nucleoside modified)	BIONTECH MANUFACTURING GmbH	New AS, New Biological, Cond auth
COVID-19 VACCINE MODERNA	COVID-19 Mrna VACCINE (nucleoside modified)	MODERNA BIOTECH SPAIN, S.L.	New AS, New Biological, Cond auth
COVID-19 VACCINE ASTRAZENECA	COVID-19 VACCINE (ChAdOx1-S [recombinant])	ASTRAZENECA AB	New AS, New Biological, Cond auth
CONVULEX	VALPROIC ACID	TAKEDA BELGIUM	PASS
CRYSVITA	BUROSUMAB	KYOWA KIRIN HOLDINGS B.V.	New AS, New Biological, Cond auth
CUTAQUIG	HUMAN NORMAL IMMUNOGLOBULIN	OCTOPHARMA GMBH	New Biological
CUVITRU	IMMUNOGLOBULIN	BAXALTA INNOVATIONS GMBH, AUSTRIA	New Biological
DARZALEX	DARATUMUMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological
DAURISMO	GLASDEGIB	PFIZER EUROPE MA EEIG	New AS
DAXAS	ROFLUMILAST	ASTRAZENECA AB	PASS
DECTOVA	ZANAMIVIR	GLAXOSMITHKLINE TRADING SERVICES B.V.	Auth under excep circumstances
DEFITELIO	DEFIBROTIDE	GENTIUM S.P.A	New Biological, Auth under excep circumstances
DELSTRIGO	DORAVIRINE/LAMIVUDINE/TENOFIVIR DISOPROXIL	MERCK SHARP & DOHME B.V.	New AS
DELTYBA	DELANAMID	OTSUKA NOVEL PRODUCTS GMBH	New AS, Conditional auth

DENGVAXIA	DENGUE TETRAVALANT VACCINE (live, attenuated)	SANOPI PASTEUR	New AS, New Biological
DEPAKINE	SODIUM VALPROATE	SANOPI BELGIUM	PASS
DEPAKINE CHRONO	SODIUM VALPROATE, VALPROIC ACID	SANOPI BELGIUM	PASS
DEPAKINE CHRONO	SODIUM VALPROATE, VALPROIC ACID	PI-PHARMA NV	PASS
DEPAKINE ENTERIC	SODIUM VALPROATE	SANOPI BELGIUM	PASS
DEPAKINE IV	SODIUM VALPROATE	SANOPI BELGIUM	PASS
DESCOVY	EMTRICITABINE, TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES IRELAND UC	New AS
DOPTELET	AVATROMBOPAG	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	New AS
DUAKLIR GENUAIR	ACLIDINIUM BROMIDE/ FORMOTERL FUMARATE DIHYDRATE	ASTRAZENECA AB	PASS
DUPIXENT	DUPIUMAB	SANOPI-AVENTIS GROUPE	New AS, New biological
EKLIRA GENUAIR	ACLIDINIUM (BROMURE)	ASTRAZENECA AB	New AS, PASS
ELAPRASE	IDURSULFASE	SHIRE HUMAN GENETIC THERAPIES AB	Auth under excep circumstances
EFLUELDA	QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOPI PASTEUR	New biological
ELEBRATO ELLIPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES LTD	New AS
ELZONRIS	TAGRAXOFUSP	STEMLINE THERAPEUTICS B.V.	New AS, New Biological, Auth under excep circumstances
EMGALITY	GALCANEZUMAB	ELI LILLY NEDERLAND BV	New AS, New Biological
ENDOLUCINBETA	LUTETIUM(177 Lu) CHLORIDE	ITG ISOTOPE TECHNOLOGIES GARCHING GMBH	New AS
ENHERTU	TRASTUZUMAB DERUXTECAN	DAIICHI SANKYO EUROPE GmbH	New AS, New biological, conditional auth
ENOXAPARIN BECAT (ALSO KNOWN IN EU COUNTRIES AS LOSIMA, ENOXAPARIN ROVI, CRUSIA AND AROVI)	ENOXAPARIN SODIUM	LABORATORIOS FARMACEUTICOS ROVI SA	New Biological
EPCLUSA	SOFOSBUVIR/ VELPATASVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS
EQUIDACENT	BEVACIZUMAB	CENTUS BIOTHERAPEUTICS EUROPE LIMITED	New Biological
ERELZI	ETANERCEPT	SANDOZ GMBH	New Biological
ERLEADA	APALUTAMIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS
ERVEBO	EBOLA ZAIRE VACCINE (rVSVΔG-ZEBOV-GP,live)	MERCK SHARP & DOHME B.V.	New AS, New Biological
ESPEROCT	TUROCTOCOG ALFA PEGOL	NOVO NORDISK A/S	New AS, New Biological, PASS
EVENITY	ROMOSUZUMAB	UCB PHARMA S.A.	New AS, New Biological
EVOLTRA	CLOFARABINE	GENZYME EUROPE B.V.	Auth under excep circumstances
EXJADE	DEFERASIROX	NOVARTIS EUROPHARM LIMITED	PASS
EXVIERA	DASABUVIR	ABBVIE LTD	PASS
FASENRA	BENRALIZUMAB	ASTRAZENECA AB	New Biological, New AS
FERCAYL	IRON DEXTRAN NON NUMERICAL AMOUNT	LABORATORIA STEROP NV	PASS

FERTINORM KIT	Gonadotrophin Postmenopausal (HMG) Non Numerical Amount quantum satis	GOODLIFE	New Biological
FETCROJA	CEFIDEROCOL	SHIONOGI B.V.	New AS
FIASP	INSULIN ASPART	NOVO NORDISK A/S	New Biological
FIBRYGA	HUMAN FIBRINOGEN	OCTAPHARMA GMBH	New Biological
FINTEPLA	FENFLURAMINE	ZOGENIX ROI Limited	PASS
FIRDAPSE	AMIFAMPRIDINE (PHOSPHATE)	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
FLIXABI	INFLIXIMAB	SAMSUNG BIOEPSIS UK Limited	New Biological
FLUAD TETRA	INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, ADJUVANTED)	SEQIRUS NETHERLANDS B.V.	New Biological
FLUCELVAX TETRA	INFLUENZA VACCINE (surface antigen, inactivated prepared in cell cultures)	SEQIRUS NETHERLANDS B.V.	New Biological
FOTIVDA	TIVOZANIB	EUSA PHARMA UK LTD	New AS
FULPHILA	PEGFILGRASTIM	MYLAN SAS	New Biological
GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS UK LTD	New AS
GAMMAPLEX 10%	HUMAN NORMAL IMMUNOGLOBULIN	BIO PRODUCTS GMBH, NEU-ISENBURG, DE	New Biological
GHEMAXAN	ENOXAPARIN SODIUM	CHEMI S.P.A.	New AS
GIAPREZA	ANGIOTENSIN II ACETATE	LA JOLLA PHARMACEUTICAL II B.V.	New AS
GILENYA	FINGOLIMOD (HYDROCHLORIDE) 0.50 MG	NOVARTIS EUROPHARM LIMITED	New AS, PASS
GIVLAARI	GIVOSIRAN	ALNYLAM NETHERLANDS B.V.	New AS
GLIVEC	IMATINIB	NOVARTIS EUROPHARM LIMITED	PASS
GLYXAMBI	EMPAGLIFOZIN/LINAGLIPTIN	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS
GRASUSTEK	PEGFILGRASTIM	JUTA PHARMA GMBH	New Biological
HALIMATOZ	ADALIMUMAB	SANDOZ GMBH	New Biological
HARVONI	LEDIPASVIR, SOFOSBUVIR	GILEAD SCIENCES IRELAND LTD	New AS
HEFIYA	ADALIMUMAB	SANDOZ GMBH	New Biological
HELEN	CHLORMADINONE, ETHINYLESTRADIOL	Mithra Pharmaceuticals S.A.	Outcome Referral Art 31, PASS
HEMLIBRA	EMICIZUMAB	ROCHE REGISTRATION GMBH	New AS, New biological
HEPAXANE	ENOXAPARIN SODIUM	CHEMI S.P.A.	New Biological
HEPCLUDEX	BULEVIRTIDE	MYR GMBH	New AS, conditional auth
HERZUMA	TRASTUZUMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
HOLOCLAR	EX VIVO EXPENDED AUTOLOGOUS HUMAN CORNEAL EPITHELIAL CELLS CONTAINING STEM CELLS	CHIESI FARMACEUTICI SPA, ITALY	New AS, Conditional auth, New biological
HULIO	ADALIMUMAB	MYLAN S.A.S.	New Biological
HYQVIA	IMMUNOGLOBULIN HUMAN NORMAL 100.00 MG/ML	BAXTER INNOVATIONS GMBH	New Biological

HYRIMOZ	ADALIMUMAB	SANDOZ GMBH	New Biological
IBRANCE	PALBOCICLIB	PFIZER LIMITED	New AS
ICLUSIG	PONATINIB	INCYTE BIOSCIENCES DISTRIBUTION B.V.	PASS
IDACIO	ADALIMUMAB	FRESENIUS KABI DEUTSCHLAND GmbH	New Biological
IDEFIRIX	IMLIFIDASE	HANSA BIOPHARMA AB	New biological
DELVION	ALBUTREPENONACOG-ALFA	CSL-BEHRING GmbH	New AS, New Biological
ILUMETRI	TILDRAKIZUMAB	ALMIRALL S.A.	New AS, New Biological
IMFINZI	DURVALUMAB	ASTRAZENECA AB	New AS, New Biological
IMNOVID (POMALIDOMIDE CELGENE)	POMALIDOMIDE	CELGENE EUROPE LIMITED	PASS
IMRALDI	ADALIMUMAB	SAMSUNG BIOEPSIS UK Limited	New AS
IMVANEX	Modified Vaccinia Ankara virus - Bavarian Nordic (MVA-BN) live virus	BAVARIAN NORDIC A/S	New AS, Auth under excep circumstances
INCRELEX	MECASERMIN	IPSEN PHARMA	Auth under excep circumstances, PASS
INCRUSE ELLIPTA	UMECLIDINIUM BROMIDE	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS
INFLUVAC TETRA	INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVED)	MYLAN IRE HEALTHCARE Ltd	New Biological
INHIXA	ENOXAPARIN SODIUM	TECHDOW PHARMA NETHERLANDS B.V.	New Biological
INJECTAFER	FERRIC CARBOXYMALTOSE	VIFOR FRANCE SA	PASS
INREBIC	FEDRATINIB	CELGENE EUROPE B.V.	New AS
INSULIN ASPART SANOFI	INSULIN ASPART	SANOFI-AVENTIS GROUPE	New Biological
INSULIN LISPRO SANOFI	INSULIN LISPRO	SANOFI-AVENTIS GROUPE	New Biological
INTRAROSA	PRASTERONE	ENDOCEUTICS Ltd	PASS
INTUNIV	Guanfacine	SHIRE PHARMACEUTICAL IRELAND LIMITED	PASS
IQYMUNE	HUMAN NORMAL IMMUNOGLOBULIN	LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES	New Biological
ISOCURAL	ISOTRETINOIN	PIERRE FABRE BENELUX	PASS
ISOSUPRA LIDOSE	ISOTRETINOIN	LABORATORIES SMB S.A.	PASS
ISOTRETINOIN EG	ISOTRETINOIN	EUROGENERICS N.V.	PASS
ISTURISA	OSILODROSTAT	NOVARTIS EUROPHARM LIMITED	New AS
ITULAZAX	STANDARDISED ALLERGEN EXTRACT FROM BIRCH	ALK-ABELLO A/S	New Biological
JAYDESS	LEVONORGESTREL 13.50 MG	BAYER AB	PASS
JINARC	TOLVAPTAN	OTSUKA PHARMACEUTICAL EUROPE LTD	PASS
JIVI	DAMOCTOCOG ALFA PEGOL	BAYER AG	New AS, New Biological, PASS
JULUCA	DOLUTEGRAVIR/RILPIVIRINE	VIIV HEALTHCARE UK LIMITED	New AS
JYSELECA	FILGOTINIB	GILEAD SCIENCES IRELAND UC	New AS
KAFTRIO	IVACAFTOR/ TEZACAFTOR/ ELEXACAFTOR	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	New AS
KANJINTI	TRASTUZUMAB	AMGEN EUROPE BV	New Biological

KANUMA	SEBELIPASE ALFA	ALEXION EUROPE SAS	New AS, PASS, New biological
KETOCONAZOLE HRA	KETOCONAZOLE	HRA PHARMA RARE DISEASES	PASS
KEVZARA	SARILUMAB	SANOFI-AVENTIS GROUPE	New AS, New biological
KISPLYX	LENVATINIB	EISAI EUROPE LIMITED	New AS
KISQALI	RIBOCICLIB	NOVARTIS EUROPHARM LIMITED	New AS
KIXELLE	INSULIN ASPART	MYLAN IRE HEALTHCARE LIMITED	New biological
KYMRIAH	TISAGENLECLEUCEL	NOVARTIS EUROPHARM LIMITED	New AS, New Biological
KYNTHEUM	BRODALUMAB	LEO PHARMA A/S	New AS
LAMZEDE	VELMANASE ALFA	CHIESI FARMACEUTICI S.P.A.	New AS, Auth under excep circumstances
LAVENTAIR ELLIPTA	UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE	GLAXO GROUP LTD	New AS, PASS
LEDRAXEN	ENOXAPARIN SODIUM	VENIPHARM	New Biological
LEMTRADA	ALEMTUZUMAB	SANOFI BELGIUM	PASS
LEQVIO	INCLISIRAN	NOVARTIS EUROPHARM LIMITED	New AS
LIBMELDY	autologous CD34+ cell enriched population that contains hematopoietic stem and progenitor cells transduced ex vivo using a lentiviral vector encoding the human arylsulfatase A gene	ORCHARD THERAPEUTICS (NETHERLANDS) B.V.	New AS, New Biological, PASS
LIBTAYO	CEMPILMAB	REGENERON IRELAND U.C.	New AS, New Biological, Conditional auth
LIMAXENTIN 4 MG/ML INJEKTIONSLOSUNG	METHACETIN	HUMEDICS GMBH	New AS
LIVOGIVA	TERIPARATIDE	THERAMEX IRELAND LIMITED	New biological
LOJUXTA	LOMITAPIDE (MESYLATE)	AMRYT PHARMACEUTICALS DAC	New AS, Auth under excep circumstances
LOKELMA	SODIUM ZIRCONIUM CYCLOSILICATE	ASTRAZENECA AB	New AS
LORVIQUA	LORLATINIB	PFIZER EUROPE MA EEIG	New AS, Conditional auth
LUMOXITI	MOXETUMOMAB PASUDOTOX	ASTRAZENECA AB	New AS, New Biological, Auth under excep circumstances
LUTATHERA	LUTETIUM (177Lu) OXODOTREOTIDE	ADVANCED ACCELERATOR APPLICATIONS	New AS
LUXTURNA	VORETIGENE NEPARVOVEC	NOVARTIS EUROPHARM LIMITED	New AS, PASS, New biological
LYUMJEV	INSULIN LISPRO	ELI LILLY NEDERLAND B.V.	New Biological
MACIMORELIN AETERNA ZENTARIS	MACIMORELIN	AETEMA ZENTARIS Gmbh	New AS
MAVIRET	GLECAPREVIR / PIBRENTASVIR	ABBVIE LTD	New AS, PASS
MAYZENT	SIPONIMOD	NOVARTIS EUROPHARM LIMITED	New AS
MEDIKINET RETARD	METHYLPHENIDATE HYDROCHLORIDE	MEDICE ARZEIMITTEL PÜTTNER GMBH CO. KG	PASS
MEKTOVI	BINIMETINIB	PIERRE FABRE MEDICAMENT	New AS
MENQUADFI	MENINGOCOCCAL GROUP A, C, W and Y CONJUGATE VACCINE	SANOFI PASTEUR	New Biological

MEPSEVII	VESTRONIDASE ALFA	ULTRAGENYX GERMANY GMBH	New AS, New Biological, Auth under excep circumstances
MOVYMIA	TERIPARATIDE	STADA ARZNEIMITTEL AG	New Biological
MULPLEO (previously LUSUTROMBOPAG SHIONOGI)	LUSUTROMBOPAG	SHIONOGI B.V.	New AS
MVABEA	EBOLA VACCINE (MVA-BN-Filo [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological, Auth under excep circumstances
MVASI	BEVACIZUMAB	AMGEN EUROPE BV	New Biological
MYALEPTA	METRELEPTIN	AMRYT PHARMACEUTICALS DAC	New AS, New Biological, Auth under excep circumstances
MYLOTARG	GEMTUZUMAB	PFIZER LIMITED	New AS, New Biological
MYSIMBA	NALTREXONE, BUPROPION	OREXIGEN THERAPEUTICS IRELAND LIMITED	PASS
NAGLAZYME	GALSULFASE	BIOMARIN EUROPE LTD	Auth under excep circumstances, PASS
NATPAR	PARATHYROID HORMONE	SHIRE PHARMACEUTICALS IRELAND LTD	Conditional auth
NEOPARIN	ENOXAPARINUM NATRICUM	SciencePharma spółka z ograniczoną odpowiedzialnością spółka komandytowa	New Biological
NEOTIGASON	ACITRETINE	AUROBINDO Pharma B.V.	PASS
NEPARVIS	SACUBITRIL/ VALSARTAN	NOVARTIS EUROPHARM LIMITED	New AS
NEPEXTO	ETANERCEPT	MYLAN IRE HEALTHCARE LIMITED	New Biological
NERLYNX	NERATINIB	PIERRE FABRE MEDICAMENT	New AS
NEXOBRID	PROTEOLYTIC ENZYMES (CONCENTRATE) ENRICHED IN BROMELAIN	MEDIWOUND GERMANY GMBH	New AS, PASS
NILEMDO	BEMPEDOIC ACID	FGK REPRESENTATIVE SERVICE GMBH	New AS
NINLARO	IXAZOMIB	TAKEDA PHARMA A/S	New AS, Conditional auth
NUBEQA	DARULOTAMIDE	BAYER AG	New AS
NUCEIVA	BOTULINUM TOXIN TYPE A	EVOLUS PHARMA LIMITED	New Biological
NUSTENDI	BEMPEDOIC ACID/ EZETIMIBE	FGK REPRESENTATIVE SERVICE GMBH	New AS
NYVEPRIA	PEGFILGRASTIM	PFIZER EUROPE MA EEIG	New Biological
OBILTOXAXIMAB SFL	OBILTOXAXIMAB	SFL PHARMACEUTICALS DEUTSCHLAND GMBH	New AS, New Biological, Auth under excep circumstances
OBIZUR	SUSOCTOCOG ALFA	BAXALTA INNOVATIONS GMBH	New AS, Auth under excep circumstances
OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMA LTD	New AS, Conditional auth
OCREVUS	OCRELIZUMAB	ROCHE REGISTRATION LIMITED	New AS
OGIVRI	TRASTUZUMAB	MYLAN S.A.S.	New Biological
OLUMIANT	BARICITINIB	ELI LILLY NEDERLAND BV	New AS
ONBEVZI	BEVACIZUMAB	SAMSUNG BIOEPSIS UK Limited	New Biological
ONDEXXYA	ANDEXANET ALFA	PORTOLA NETHERLANDS BV	New AS, New Biological, Conditinal auth
ONGENTYS	OPICAPONE	BIAL - PORTELA & C ^a , SA	New AS

ONPATTRO	PATISIRAN	ALNYLAM NETHERLANDS BV	New AS
ONTRUZANT	TRASTUZUMAB	SAMSUNG BIOEPSIS UK Limited	New Biological
ORCHIDEA	CHLORMADINONE, ETHINYLESTRADIOL	MEDA PHARMA	Outcome Referral Art 31, PASS
ORKAMBI	LUMACAFITOR / IVACAFITOR	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	PASS
ORPHACOL	CHOLIC ACID	LABORATOIRES CTRS	Auth under excep circumstances
OXERVATE	CENEGERMIN	DOMPE FARMACEUTICI S.p.a.	New AS
OXLUMO	LUMASIRAN	ALNYLAM NETHERLANDS BV	New AS
OZADUB	OZENAXACIN	FERRER INTERNACIONAL S.A.	New AS
OZEMPIC	SEMAGLUTIDE	NOVO NORDISK A/S	New AS
PALYNZIQ	PEGVALIASE	BIOMARIN INTERNATIONAL LTD	New AS, New Biological
PANDEMIC INFLUENZA VACCINE H5N1 MEDIMMUNE	PANDEMIC INFLUENZA VACCINE (H5N1)(live attenuated, nasal)	ASTRAZENECA AB	New AS, Conditional auth
PARSABIV	ETELCALCETIDE	AMGEN EUROPE BV	New AS
PELGRAZ	PELFILGRATIM	ACCORD HEALTHCARE LIMITED	New Biological
PELMEG	PEGFILGRASTIM	MUNDIPHARMA BIOLOGICS S.L.	New Biological
PENTHROX	MEHOXYFLURANE	MEDICAL DEVELOPMENTS UK LTD	PASS
PHESGO	PERTUZUMAB/ TRASTUZUMAB	ROCHE REGISTRATION GMBH	New Biological
PIFELTRO	DORAVIRINE	MERCK SHARP & DOHME LTD	New AS
PLASMAVOLUME REDIBAG 6%	HYDROXYETHYL STARCH	BAXTER S.A.	Outcome Referral Art 31, PASS
PIQRAY	ALPELISIB	NOVARTIS EUROPHARM LIMITED	New AS
POLIVY	POLATUZUMAB VEDOTIN	ROCHE REGISTRATION GMBH	New AS, New Biological, Conditional auth
PORTRAZZA	NECITUMUMAB	ELI LILLY NEDERLAND BV	New AS
POTELIGEO	MOGAMULIZUMAB	KYOWA KIRIN HOLDINGS B.V.	New AS, New Biological
PREVYMIS	LETERMOVIR	MERCK SHARP & DOHME LTD	New AS
PRETOMANID FGK	PRETOMANID	FGK REPRESENTATIVE SERVICE GMBH	New AS, conditional auth
QARZIBA	DINUTUXIMAB BETA	EUSA PHARMA UK LTD	New Biological, PASS, Auth under excep circumstances
QUINSAIR	LEVOFLOXACIN	CHIESI FARMACEUTICI S.P.A.	PASS
QUOFENIX	DELAFLOXACIN	A.MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	New AS
RAGWIZAX	STANDARDIZED ALLERGEN EXTRACT FROM POLLEN FROM SHORT RAGWEED (AMBROSIA ARTEMISIFOLIA)	ALK-ABELLO A/S	New Biological
RAPIBLOC	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS	New AS
RAVICTI	GLYCEROL PHENYL BUTYRATE	IMMEDICA PHARMA AB	New AS, PASS
RAXONE	IDEBENONE	SANTHERA PHARMACEUTICALS (Deutschland) GmbH	Auth under excep circumstances
REAGILA	CARIPRAZINE	GEDEON RICHTER Plc	New AS

REBLOZYL	LUSPATERCEPT	CELGENE EUROPE B.V.	New AS
RECARBIO	IMIPENEM/CILASTATIN/RELEBACTAM	MERCK SHARP & DOHME B.V.	New AS
REFIXIA	NONACOG BETA PEGOL	NOVO NORDISK A/S	New AS, PASS, New Biological
REKAMBYS	RILPIVIRINE	JANSSEN-CILAG INTERNATIONAL NV	PASS
REKOVELLE	FOLLITROPIN ALPHA	FERRING PHARMACEUTICALS A/S	New Biological
RETSEVMO	SELPERCATINIB	ELI LILLY NEDERLAND B.V.	New AS, Conditional auth
REVESTIVE	TEDUGLUTIDE	SHIRE PHARMACEUTICALS IRELAND LTD	New AS, PASS
REVLIMID	LENALIDOMIDE	BRISTOL-MYERS SQUIBB PHARMA EEIG	PASS
RHOKIINSA	NETARSUDIL	AEIRE PHARMACEUTICALS IRELAND LTD	New AS
RINVOQ	UPADACITINIB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS
RITEMVIA	RITUXIMAB	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
RIXATHON	RITUXIMAB	SANDOZ GMBH	New Biological
RIXIMYO	RITUXUMAB	SANDOZ GMBH	New Biological
RIZMOIC	NALDEMEDINE	SHIONOGI B.V.	New AS
ROACCUTANE	ISOTRETINOIN	N.V. ROCHE S.A.	PASS
ROCLANDA	LATANOPROST/ NETARSUDIL	AERIE PHARMACEUTICALS IRELAND Ltd	New AS
ROLUFTA ELLIPTA	UMECLIDINIUM	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS, PASS
ROTEAS	EDOXABAN	BERLIN-CHEMIE AG	New AS
ROZLYTREK	ENTRECTINIB	ROCHE REGISTRATION GMBH	New AS, conditional auth
RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY UK LIMITED	New AS, Conditional auth
RUKOBIA	FOSTEMSAVIR	VIIV HEALTHCARE BV	New AS
RUXIENCE	RITUXIMAB	PFIZER EUROPE MA EEIG	New Biological
RXULTI	BREPIRAZOLE	OTSUKA PHARMACEUTICAL EUROPE LTD	New AS
RYBELSUS	SEMAGLUTIDE	NOVO NORDISK A/S	New biological
RYDAPT	MIDOSTAURIN	NOVARTIS EUROPHARM LIMITED	New AS
SARCLISA	ISATUXIMAB	SANOFI-AVENTIS GROUPE	New AS, New Biological
SCENESSE	AFAMELANOTIDE	CLINUVEL UK LIMITED	New AS, Auth under excep circumstances
SEASONIQUE	LEVONORGESTREL, ETHINYLESTRADIOL	THERAMEX	PASS
SEGLUOMET	ERTUGLIFLOZIN/ METFORMIN HYDROCHLORIDE	MERCK SHARP & DOHME B.V.	New AS
SEMGLEE	INSULIN GLARGINE	MYLAN SAS	New Biological
SENSHIO	OSPEMIFENE	SHIONOGI LIMITED	New as, PASS
SHINGRIX	HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)	GLAXOSMITHKLINE BIOLOGICALS S.A.	New AS
SIRTURO	BEDAQUILINE	JANSSEN-CILAG INTERNATIONAL NV	New AS, Conditional auth
SIXMO	BUPRENORPHINE	L.MOLTENI & C. dei F.Ili Alitti Soc.Es.S.p.A.	New Biological, PASS

SKUDEXA (also known in some EU countries as Enanplus, Skudexum and Lenizak)	TRAMADOL HYDROCHLORIDE/ DEXKETOPROFEN	LABORATOIRE MENARINI	PASS
SKYRIZI	RISANKIZUMAB	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS, New Biological
SOMAKIT TOC	EDOTREOTIDE	Advanced Accelerator Applications	New AS
SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INTERNATIONAL LTD	New AS
SPHEROX	SPHEROIDS OF HUMAN AUTOLOGOUS MATRIX-ASSOCIATED CHONDROCYTES	CO.DON AG	New AS
SPINRAZA	NUSINERSEN	BIOGEN NETHERLANDS B.V.	New AS
SPRAVATO	ESKETAMINE	JANSSEN-CILAG INTERNATIONAL NV	Restrictions with regards to the safe and effective use of the medicinal product
STAQUIS	CRISABOROLE	PFIZER EUROPE MA EEIG	New AS
STEGLATRO	ERTUGLIFLOZIN	MERCK SHARP & DOHME B.V.	New AS
STEGLUJAN	ERTUGLIFLOZIN/ SITAGLIPTIN	MERCK SHARP & DOHME B.V.	New AS
STRENSIQ	ASFOTASE ALFA	ALEXION EUROPE SAS	New AS, Aut under excep circumstances
STRIMVELIS	AUTOLOGOUS CD34 + ENRICHED CELL FRACTION THAT CONTAINS CD34 + CELLS TRANSDUCED WITH RETROVIRAL VECTOR THAT ENCODES FOR THE HUMAN ADA Cdna SEQUENCE	ORCHARD THERAPEUTICS (NETHERLANDS) B.V.	New AS, PASS
STRIVERDI RESPIMAT	OLODATEROL	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	New AS, PASS
SUBLIVAC BAUME	ALLERGEN EXTRACT OF POLLEN FROM BIRCH, ALDER AND HAZEL	HAL ALLERGIE GMBH	New Biological
SUBLIVAC BIRKE	ALLERGEN EXTRACT OF POLLEN FROM BIRCH	HAL ALLERGIE GMBH	New Biological
SULIQUA	INSULINE GLARGINE/ LIXISENATIDE	SANOFI-AVENTIS GROUPE	New AS
SULOVAS	SULOXIDE	AFLOFARM FARMACJA POLSKA SP. Z o.o.	New Biological
SUPEMTEK	QUADRIVALENT INFLUENZA VACCINE (RECOMBINANT, PREPARED IN CELL CULTURE)	SANOFI PASTEUR	New Biological
SUNOSI	SOLRIAMFETOL	JAZZ PHARMACEUTICALS IRELAND LTD	New AS
SYLVANT	SILTUXIMAB	EUSA PHARMA NETHERLANDS B.V.	New AS
SYMKEVI	TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS (IRELAND) LIMITED	New AS
SYMTUZA	DARUNAVIR/COBICISTAT/EMTRICITABINE/ TENOFOVIR ALAFENAMIDE	JANSSEN-CILAG INTERNATIONAL NV	New AS
TAGRISSO	OSIMERTINIB	ASTRAZENECA AB	New AS, Conditional auth
TAKHZYRO	LANADELUMAB	SHIRE PHARMACEUTICALS IRELAND LTD	New AS, New Biological
TAKUDEX	TRAMADOL HYDROCHLORIDE/ DEXKETOPROFEN	GUIDOTTI FARMA	PASS
TALZENNA	TALAZOPARIB	PFIZER EUROPE MA EEIG	New AS
TARGOCID	TEICOPLANINE	SANOFI-AVENTIS BELGIUM	Outcome Referral Art 31, PASS

TAVLESSE	FOSTAMATINIB	INSTITUTO GRIFOLS SA	New AS
TECARTUS	autologous anti-CD19-transduced CD3+ cells	KITE PHARMA EU B.V.	New AS, New Biological, Cond auth, PASS
TECENTRIQ	ATEZOLIZUMAB	ROCHE REGISTRATION LIMITED	New AS
TEGSEDI	INOTERSEN	AKCEA THERAPEUTICS UK LTD	New AS
TEMYBRIC ELIPPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES	New AS
TERROSA	TERIPARATIDE	GEDEON RICHTER	New Biological
TETRASPAN 10%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
TETRASPAN 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
THIOSIX	TIOGUANIN	TEVA NEDERLAND B.V.	Auth under excep circumstances
TOOKAD	PADELIPORFIN	STEBA BIOTECH SA	New AS
TRANSLARNA	ATALUREN	PTC THERAPEUTICS LTD	New AS, Conditional auth
TRAZIMERA	TRASTUZUMAB	PFIZER EUROPE MA EEG	New Biological
TRELEGY ELLIPTA	FLUTICASONE FUROATE/ UMECLIDINIUM/ VILANTEROL	GLAXOSMITHKLINE TRADING SERVICES LIMITED	New AS
TREMFYA	GUSELKUMAB	JANSSEN-CILAG INTERNATIONAL NV	New AS
TRIVALENT INFLUENZA VACCINE	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOVI PASTEUR	New Biological
TROGARZO	IBALIZUMAB	THERATECHNOLOGIES EUROPE LIMITED	New AS, New Biological
TRUMENBA	MENINGOCOCCAL GROUP B VACCINE (RECOMBINANT, COMPONENT, ADSORBED)	PFIZER EUROPE MA EEIG	New AS, New Biological
TRUXIMA	RITUXIMA	CELLTRION HEALTHCARE HUNGARY KFT.	New Biological
TUKYSA	TUCATINIB	SEAGEN B.V.	New AS
TYSABRI	NATALIZUMAB	BIOGEN NETHERLANDS B.V.	PASS
UDENYCA	PEGFILGRASTIM	ERA CONSULTING GmbH	New Biological
ULTOMIRIS	RAVULIZUMAB	ALEXION EUROPE SAS	New AS, New Biological
VABOREM	MEROPENEM/ VABORBACTAM	MENARINI INTERNATIONAL OPERATIONS Luxembourg SA	New AS
VALPROATE MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS
VALPROATE RETARD EG	SODIUM VALPROATE, VALPROIC ACID	EUROGENERICS N.V.	PASS
VALPROATE RETARD MYLAN	SODIUM VALPROATE	MYLAN BVBA	PASS
VALPROATE SANDOZ	SODIUM VALPROATE, VALPROIC ACID	SANDOZ NV	PASS
VAXCHORA	CHOLERA VACCINE (RECOMBINANT, LIVE, ORAL)	EMERGENT NETHERLANDS B.V.	New AS, New biological
VAXIGRIP TETRA	INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)	SANOVI PASTEUR EUROPE	New Biological
VEDROP	TOCOPHEROL D-ALPHA (AS TOCOFERSOLAN)	RECORDATI RARE DISEASES	Auth under excep circumstances, PASS
VEKLURY	REMDESIVIR	GILEAD SCIENCES IRELAND UC	New AS, Conditional auth
VELTASSA	PATIROMER	Vifor Fresenius Medical Care Renal Pharma France	New AS
VEMLIDY	TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES IRELAND LTD	New AS
VENCLYXTO	VENETOCLAX	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS, Conditional auth

VENOFER	IRON SUCROSE	VIFOR FRANCE	PASS
VENOHES 6%	HYDROXYETHYL STARCH	B. BRAUN MELSUNGEN AG	Outcome Referral Art 31, PASS
VERASEAL	HUMAN FIBRINOGEN/ HUMAN THROMBIN	INSTITUTO GRIFOLS SA	New Biological
VERZENIOS	ABEMACICLIB	ELI LILLY NEDERLAND BV	New AS
VEYVONDI	VONICOG ALFA	BAXALTA INNOVATIONS GMBH	New AS, New Biological
VIEKIRAX	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE DEUTSCHLAND GMBH & CO. KG	New AS
VIHUMA	SIMOCTOCOG ALFA	OCTOPHARMA AB	New AS
VIMIZIM	ELOSULFASE ALFA	BIOMARIN INTERNATIONAL LTD	New AS, PASS
VITRAKVI	LAROTRECTINIB	BAYER AG	Conditional auth, New AS
VIZIMPRO	DACOMITINIB	PFIZER EUROPE MA EEIG	New AS
VOCABRIA	CABOTEGRAVIR	VIIV HEALTHCARE BV	New AS, PASS
VOLULYTE 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 10%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOLUVEN 6%	HYDROXYETHYL STARCH	FRESENIUS KABI NV	Outcome Referral Art 31, PASS
VOSEVI	SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	GILEAD SCIENCES INTERNATIONAL LIMITED	New AS, PASS
VYNDAQEL	TAFAMIDIS (MEGLUMINE)	PFIZER EUROPE MA EEG	Auth under excep circumstances, New AS, PASS
WAKIX	PITOLISANT HYDROCHLORIDE	BIOPROJET PHARMA	PASS
WAYLIVRA	VOLANESORSEN	AKCEA THERAPEUTICS IRELAND LTD	New AS, Conditional auth
XARELTO	RIVAROXABAN	BAYER PHARMA AG	PASS
XELJANZ	TOFACITINIB	PFIZER LIMITED	New AS
XENLETA	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	New AS
XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS IRELAND LIMITED	New AS
XERMELO	TELOTTRISTAT	IPSEN PHARMA	New AS
XOFIGO	Radium Ra 223 dichloride	BAYER PHARMA AG	PASS
XOFLUZA	BALOXAVIR MARBOXIL	ROCHE REGISTRATION GMBH	New AS
XOSPATA	GILTERITINIB	ASTELLAS PHARMA EUROPE BV	New AS
YESCARTA	AXICABTAGENE CILOLEUCEL	KITE PHARMA EU BV	New AS, New Biological, PASS
ZABDENO	EBOLA VACCINE (Ad26.ZEBOV-GP [recombinant])	JANSSEN-CILAG INTERNATIONAL NV	New AS, New biological, Auth under excep circumstances
ZAVICEFTA	CEFTAZIDIME/ AVIBACTAM	PFIZER IRELAND PHARMACEUTICALS	New AS
ZEJULA	NIRAPARIB	GLAXOSMITHKLINE (IRELAND) LIMITED	New AS
ZERCEPAC	TRASTUZUMAB	ACCORD HEALTHCARE S.L.U.	New AS, New Biological
ZEPATIER	ELBASVIR/GRAZOPREVIR	MERCK SHARP & DOHME LTD	New AS
ZEPOSIA	OZANIMOD	BRISTOL-MYERS SQUIBB PHARMA EEIG	New AS
ZESSLY	INFLIXIMAB	SANDOZ GMBH	New Biological
ZIEXTENZO	PEGFILGRASTIM	SANDOZ GMBH	New Biological
ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME LTD	New AS

ZIRABEV	BEVACIZUMAB	PFIZER EUROPE MA EEIG	New Biological
ZOELY	NOMOGESTROL ACETATE / ESTRADIOL HEMIHYDRATE	THERAMEX IRELAND LIMITED	PASS
ZOLGENSMA	ONASEMNOGENE ABEPARVOVEC	AVEXIS EU LIMITED	New AS, New biological, conditional auth
ZYKADIA	CERITINIB	NOVARTIS EUROPHARM LIMITED	New AS, Conditional auth
ZYNQUISTA	SOTAGLIFOZIN	NAVIGANT GERMANY GMBH	New AS
ZYNTEGLO	AUTOLOGOUS CD34 + CELLS ENCODING β A-T87Q-GLOBINGENE	BLUEBIRD BIO (NETHERLANDS) B.V.	New AS

NOTE	
In Red	commercialised / commercialisé / gecommmercialiseerd
in Black	not commercialised / pas commercialisé / niet gecommmercialiseerd
in blue	info not yet available / info pas encore disponible / info nog niet beschikbaar
in grey	New addition of this month / nouvelle addition de ce mois / nieuwe toevoeging van deze maand
New AS	nouvelle substance active / nieuw actief bestanddeel
New Biological	nouveau médicament biologique / nieuwe biologische geneesmiddel
PASS	Etude de sécurité post-autorisation / post-autorisatie veiligheidsstudies
Conditional auth	Autorisé sous certaines conditions / vergund onder bepaalde voorwaarden
Auth under excep circumstances	autorisé sous circonstances exceptionnelles / vergund onder uitzonderlijke omstandigheden

Product informations / informations : informations sur les produits/productinformatie

http://www.fagg-afmps.be/search?language=fr&search_field=notice