

NOTICE AND DECISION ON THE CESSATION OF THE MARKETING AUTHORISATION (“SUNSET CLAUSE”)

2021

Marketing Authorisations granted in Norway 01.01.2018 - 31.12.2018 (Table 1.)

Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2021 (Table 2.)

The deadline for an exemption application is: 31.12.2021

Pursuant to § 16 of the Civil Services Act Marketing Authorisation Holders (MAHs) are hereby given notice that the Norwegian Medicines Agency is considering making a decision with regard to the cessation of the marketing authorisation for the below mentioned medicinal products:

Table 1 - Marketing Authorisations granted in Norway 01.01.2018- 31.12.2018

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Purimmun	Merkaptopurin	2care4 Generics
Zoledo	Zoledronsyre	Accord Healthcare
Cytarabine Accord	Cytarabin	Accord Healthcare
Fosaprepitant Accord	Fosaprepitantdimeglumin	Accord Healthcare
Lamivudine/Zidovudine Accord	Lamivudin, Zidovudin	Accord Healthcare
Meropenem Accord	Meropenemtrihydrat	Accord Healthcare
Diazepam Accord	Diazepam	Accord Healthcare
Cimicum	Prikkperikum, Klaseormedruerot	ARAC AT
Ursogrix	Ursodeoksykolsyre	AS Grindeks
Oxycodone Kalceks	Oksykodonhydroklorid	AS Kalceks
Canishield vet	Deltametrin	Beaphar B.V
Klimadynon	Klaseormedruerot	Bionorica SE
Zelys vet	Pimobendan til dyr	Ceva Santé Animale
Amlodipin Essential Pharmaceuticals	Amlodipinbesilat	Essential Pharmaceuticals
Sefitude	Valerianarot	Florealis
Calrecia	Kalsiumkloriddihydrat	Fresenius Medical Care
Omeprazol Hexal	Omeprazol	Hexal
Alfaxan Multidose	Alfaksalon	Jurox (Ireland) Limited
Everolimus Krka	Everolimus	KRKA, d.d. Novo mesto
Vildagliptin Krka	Vildagliptin	KRKA, d.d. Novo mesto
Dexacortone vet	Deksametason	Le Vet Beheer
Temprace vet	Acepromazin	Le Vet Beheer
Fludeomap	Fludeoksyglukose (18F)	MAP Medical Technologies OY
Borxam	Bortezomibmannitolboronat	Maxmind Pharmaceutical, S.L.U.

Duloxetine Medical Valley	Duloksetinhydroklorid	Medical Valley Invest
Diklofenaknatrium Medical Valley	Diklofenaknatrium	Medical Valley Invest
Bortezomib Medical Valley	Bortezomibmannitolboronat	Medical Valley Invest
Darunavir Medical Valley	Darunavirpropylenglykolat	Medical Valley Invest
Tramadol Medical Valley	Tramadolhydroklorid	Medical Valley Invest
Ezetimib Medical Valley	Ezetimib	Medical Valley Invest
Ebastin Medreich	Ebastin	Medreich
Everolimus Mylan	Everolimus	Mylan AB
Sirkava	Tiotropium	Mylan AB
Dexmedetomidine Mylan	Deksmedetomidinhydroklorid	Mylan AB
Paracetamol Benel	Paracetamol	Nutra Essential OTC
Travatan	Travoprost	Orifarm
Dostinex	Kabergolin	Orifarm
Olmotec	Olmesartanmedoksomil	Orifarm
Raxone	Idebenon	Orifarm
Reletrans	Buprenorfin	Orifarm
BuTrans	Buprenorfin	Orifarm
Jentadueto	Linagliptin, Metforminhydroklorid	Orifarm
Constella	Linaklotid	Orifarm
Betaferon	Interferon beta-1b	Orifarm
Comtan	Entakapon	Orifarm
Nimotop	Nimodipin	Orifarm
Nplate	Romiplostim	Orifarm
Tobradex	Tobramycin, Deksametason	Orifarm
Divisun	Kolekalsiferol	Orifarm
Buccolam	Midazolamhydroklorid	Orifarm
Gardasil 9	Vaksine	Orifarm
Mekinist	Trametinib	Orifarm
Plavix	Klopidogrelhydrogensulfat	Orifarm
Benzydamin Orifarm	Benzydaminhydroklorid	Orifarm Generics
Xylodex	Xylometazolinhydroklorid, Dekspantenol	Orifarm Generics
Paracoff	Paracetamol, Koffein	Orifarm Generics
Salflumix Easyhaler	Salmeterolxinafoat, Flutikasonpropionat	Orion Corporation
Lenalidomide Sandoz	Lenalidomid	Sandoz
Dutasteride/Tamsulosin Sandoz	Dutasterid, Tamsulosinhydroklorid	Sandoz
Biseltoc	Pentoksyverinhydrogensitrat	Sanofi-aventis Norge
Bortezomib Stada	Bortezomibmannitolboronat	Stada Arzneimittel
Bascellex	Imikvimod	Sun Pharmaceutical
Paroex	Klorheksidindiglukonat	Sunstar France

Sunitinib Teva	Sunitinib	Teva
Lenalidomide Teva	Lenalidomid	Teva
Melatonin Teva	Melatonin	Teva
Biocom P Vet	Vaksine	United Vaccines Holding
Distemink Vet	Vaksine	United Vaccines Holding
Apivar vet	Amitraz	Veto Pharma Sas
Eradia	Metronidazol	Virbac
Monurelle	Fosfomycintrometamol	Zambon SpA

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2021

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Duloxetine Accord	Duloksetinhydroklorid	Accord Healthcare
Rasagilin Accord Healthcare	Rasagilin	Accord Healthcare
Rosuvastatin Accord	Rosuvastatinkalsium	Accord Healthcare
Fluvastatin Accord	Fluvastatinnatrium	Accord Healthcare
Irbesartan Accord	Irbesartan	Accord Healthcare
Atorvastatin Actavis	Atorvastatinkalsium	Actavis Group
Bosentan Actavis	Bosentanmonohydrat	Actavis Group
Buprenorphine Actavis	Buprenorfinhydroklorid	Actavis Group
Mirtazapin Actavis	Mirtazapin	Actavis Group
Tolterodin Actavis	Tolterodintartrat	Actavis Group
diTekiBooster	Vaksine	AJ Vaccines
Veropol	Vaksine	AJ Vaccines
Bupivacaine Alternova	Bupivakainhydroklorid	Alternova
Aripiprazole Aristo	Aripiprazol	Aristo Pharma
Eurican DHPPi2-L3	Vaksine	Boehringer Ingelheim Animal Health Nordics
Eurican L3	Vaskine	Boehringer Ingelheim Animal Health Nordics
Srivasso	Tiotropiumbromid	Boehringer Ingelheim International
Yanimo Respimat	Tiotropiumbromid/Olodaterol	Boehringer Ingelheim International
Givix vet	Klindamycinhydroklorid	Ceva Santé Animale
Epirubicin Ebewe	Epirubicinhydroklorid	EBEWE Pharma
Fludarabin Ebewe	Fludarabinfosfat	EBEWE Pharma
Lisinopril EssPharm	Lisinoprilhydrat	Essential Pharmaceuticals
Adenosin Fresenius Kabi	Adenosin	Fresenius Kabi Norge
Geloplasma	Gelatin, modifisert, flytende, natriumklorid, kaliumklorid,	Fresenius Kabi Norge

	magnesiumkloridheksahydrat, natrium (s) laktat	
Zoledronsyre Richter	Zoledronsyremonohydrat	Gedeon Richter
Zoledronsyre Gedeon Richter	Zoledronsyremonohydrat	Gedeon Richter
Infanrix Polio	Vaksine	GlaxoSmithKline
Paracetamol/Phenylephrine Hermes	Paracetamol/Fenylefrinhydroklorid	Hermes Arzneimittel
Porcilis M1 ID	Vaksine	Intervet International
Mirtin	Mirtazapin	KRKA Sverige
Montelukast Krka	Montelukastnatrium	KRKA Sverige
Quetiapine Krka	Kvetiapinfumarat	KRKA Sverige
Pregabalin Krka	Pregabalin	KRKA, d.d. Novo mesto
Ziqamil vet	Milbemycinoksim/Prazikvantel	KRKA, d.d. Novo mesto
Pemetrexed Reig Jofre	Pemetrekseddinatrium	Laboratorio Reig Jofre
Iren/Iren 28	Etinyløstradiol/Drospirenon	Laboratorios Leon Farma
Ospen	Etinyløstradiol/Drospirenon	Laboratorios Leon Farma
Rosal 28	Etinyløstradiol/Drospirenon	Laboratorios Leon Farma
Naiwanel/ Naiwanel 28	Etinyløstradiol/Drospirenon	Medical Valley
Ospen 28	Etinyløstradiol/Drospirenon	Medical Valley
Rosal	Etinyløstradiol/Drospirenon	Medical Valley
Aripiprazole Medical Valley	Aripiprazol	Medical Valley Invest
Amoxicillin MIP Pharma	Amoxicillintrihydrat	MIP Pharma
Dolatramyl	Tramadolhydroklorid	Mylan
Fentanyl Mylan	Fentanyl	Mylan
Irbesartan Mylan	Irbesartan	Mylan
Valaciclovir Mylan	Valaciklovirhydroklorid	Mylan
Vancomycin Mylan	vankomycinhydroklorid	Mylan Ireland
Kaliumklorid Noridem	Kaliumklorid	Noridem Enterprises
Natriumklorid Noridem	Natriumklorid	Noridem Enterprises
Sterilt vann Noridem	Vann til injeksjonsvæsker	Noridem Enterprises
Benlysta	Belimumab	Orifarm
Candidas	Kaspofunginacetat	Orifarm
Enbrel	Etanercept	Orifarm
Epiduo	Adapalen/Benzoylperoksid	Orifarm
Estalis	Østradiolhemihydrat/Noretisteronacetat	Orifarm
Ferinject	Jern	Orifarm
Forsteo	Teriparatid	Orifarm
Forxiga	Dapagliflozin	Orifarm
Mezavant	Mesalazin	Orifarm
Orfiril long	Natriumvalporat	Orifarm
Parvoruvac	Vaksine	Orifarm

Profender	Prazikvantel/Emodepsid	Orifarm
Voltaren	Diklofenaknatrium	Orifarm
Alfacalcidol Orifarm	Alfakalsidol	Orifarm Generics
Clindamycin Orifarm	Klindamycinhydroklorid	Orifarm Generics
Frivelle	Levonorgestrel	Orifarm Generics
Nicabate	Nikotinresinat	Perrigo Sverige
Desfluran Piramal	Desfluran	Piramal Critical Care
Calima	Etinyløstradiol/Drospirenon	Sandoz
Calima 28	Etinyløstradiol/Drospirenon	Sandoz
Delamonie	Desogestrel	Sandoz
Fulvestrant Sandoz	Fulvestrant	Sandoz
Levetiracetam Sandoz	Levetiracetam	Sandoz
Mirtazapin Sandoz	Mirtazapin	Sandoz
Piperacillin/Tazobactam Sandoz	Piperacillinnatrium/Tazobaktamnatrium	Sandoz
Solifenacin Sandoz	Solifenacinsuksinat	Sandoz
Tolterodine Sandoz	Tolterodintartrat	Sandoz
Topiramat Sandoz	Topiramat	Sandoz
Zoledronsyre Sandoz	Zoledronsyremonohydrat	Sandoz
Pentavac	Vaksine	Sanofi Pasteur Europe
Bisolaclar	Acetylcystein	Sanofi-Aventis Norge
Jiskyn	Bendamustinhydroklorid	Synthon
Ipandin	Ibuprofen	Teva B.V
Tadalafil Teva	Tadalafil	Teva Sweden
Varena 28	Etinyløstradiol/Drospirenon	Teva Sweden
Varenelle 28	Etinyløstradiol/Drospirenon	Teva Sweden
Dretine/Dretine 28	Etinyløstradiol/Drospirenon	Theramex Ireland
Dretinelle/Dretinelle 28	Etinyløstradiol/Drospirenon	Theramex Ireland
Varena	Etinyløstradiol/Drospirenon	Theramex Ireland
Varenelle	Etinyløstradiol/Drospirenon	Theramex Ireland
Efficanix	Fipronil/Permetrin	Virbac

If the information on the marketing status for the products in this list is inaccurate: the appropriate information must be provided to the Norwegian Medicines Agency no later than 31.12.2021

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2021, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**