

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

2024

Marketing Authorisations granted in Norway 01.01.2021 - 31.12.21

The deadline for an exemption application is: 31.12.2024

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:

Marketing Authorisations granted in Norway 01.01.2021- 31.12.2021

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Isotracin	Isotretinoiin	2care4 Generics ApS
Dexamcol	Deksametasonnatriumfosfat, Kloramfenikol	2care4 Generics ApS
Wakix	Pitolisanthydroklorid	Abacus Medicine A/S
Tecfidera	Dimetylfumarat	Abacus Medicine A/S
Lorviqua	Lorlatinib	Abacus Medicine A/S
Celecoxib Accord	Celekoksib	Accord Healthcare B.V.
Anagrelid Accordpharma	Anagrelidhydroklorid	Accord Healthcare B.V.
Ondansetron Accordpharma	Ondansetronhydrokloriddihydrat	Accord Healthcare B.V.
Clozapine Accord	Klozapin	Accord Healthcare B.V.
Wynzora	Kalsipotriol, Betametasondipropionat	Almirall, S.A.
Ambrisentan AOP	Ambrisentan	Aop Orphan Pharmaceuticals GmbH
Paracetamol Baxter Viaflo	Paracetamol	Baxter Holding B.V.
Bortezomib Baxter	Bortezomibmannitolboronat	Baxter Holding B.V.
Fingolimod Bluefish	Fingolimodhydroklorid	Bluefish Pharmaceuticals AB
Clobazam Essential Pharmaceuticals	Klobazam	Essential Pharmaceuticals Limited
Epaclob	Klobazam	Ethypharm
Everolimus Ethypharm	Everolimus	Ethypharm
Oxycodone Ethypharm	Oksykodonhydroklorid	Ethypharm
Azacitidine Ever Pharma	Azacitidin	EVER Valinject GmbH
Bortezomib EVER Pharma	Bortezomib	EVER Valinject GmbH
Fingolimod Fresenius Kabi	Fingolimodhydroklorid	FRESENIUS KABI NORGE AS
Lenalidomide Fresenius Kabi	Lenalidomid	FRESENIUS KABI NORGE AS
Noradrenalin Fresenius Kabi	Noradrenalin tartrat	FRESENIUS KABI NORGE AS
Dexmedetomidine Kabi	Deksmedetomidinhydroklorid	FRESENIUS KABI NORGE AS
Levosimendan Fresenius Kabi	Levosimendan	FRESENIUS KABI NORGE AS
Icatibant Fresenius	Ikatibantacetat	FRESENIUS KABI NORGE AS
Ketosteril	Hydroksy-metioninkalsium, Keto-isoleucinkalsium, Keto-leucinkalsium, Keto-fenylalaninkalsium, Keto-valinkalsium, Histidin, Lysinacetat, Treonin, Tryptofan, Tyrosin	FRESENIUS KABI NORGE AS
Cifoban	Natriumsitratdihydrat	Fresenius Medical Care Deutschland GmbH
Glucopet	Fludeoksyglukose (18F)	GE Healthcare B.V.
Levosertone	Levonorgestrel	Gedeon Richter Plc.
Azacitidine Glenmark	Azacitidin	Glenmark Arzneimittel GmbH

Cabazitaxel Glenmark	Kabazitaksel	Glenmark Arzneimittel GmbH
Sugammadex hameln	Sugammadeksatrium	hameln pharma GmbH
Midazolam hameln	Midazolamhydroklorid	hameln pharma GmbH
Dexamethasone phosphate Hameln	Deksametasonnatriumfosfat	hameln pharma GmbH
Albumin Grifols	Albumin, humant	Instituto Grifols S.A
Sunitinib Krka	Sunitinibmaleat	KRKA, d.d. Novo mesto
Ticagrelor Krka	Tikagrelor	KRKA, d.d. Novo mesto
Fingolimod Krka	Fingolimodhydroklorid	KRKA, d.d. Novo mesto
Icatibant Aguettant	Ikatibantacetat	Laboratoire Aguettant
Abirateron medac	Abirateronacetat	Medac - Gesellschaft für klinische Spezialpräparate GmbH - Wedel
Hydroxyzine Medical Valley	Hydroksyzinhydroklorid	Medical Valley Invest AB
Sitagliptin Medical Valley	Sitagliptinhydroklorid	Medical Valley Invest AB
Cabazitaxel Medical Valley	Kabazitaksel	Medical Valley Invest AB
Permethrin Morningside	Permetrin	Morningside Healthcare (Malta) Limited
Simvastatin Mylan	Simvastatin	Mylan AB
Sorafenib Mylan	Sorafenibtosylat	Mylan AB
Vildagliptin Mylan	Vildagliptin	Mylan AB
Sitagliptin Mylan	Sitagliptin	Mylan AB
Golpimec	Fingolimodhydroklorid	Neuraxpharm Sweden AB
Bupivacaine Noridem	Bupivakainhydrokloridmonohydrat	Noridem Enterprises Ltd.
Zeposia	Ozanimodhydroklorid	Orifarm AS
Venclyxto	Venetoklaks	Orifarm AS
Ozurdex	Deksametason	Orifarm AS
Vitrakvi	Larotrektrinibisulfat	Orifarm AS
Vizimpro	Dakomitinibmonohydrat	Orifarm AS
Sativex	Dronabinol, Cannabidiol	Orifarm AS
Binosto	Alendronatnatriumtrihydrat	Orifarm AS
Zoledronic acid Fresenius Kabi	Zoledronsyremonohydrat	Orifarm AS
Velbe	Vinblastinsulfat	Orifarm AS
Buvidal	Buprenorfin	Orifarm AS
Voriconazole Accord	Vorikonazol	Orifarm AS
Relvar Ellipta	Flutikasonfuroat, Vilanteroltrifenatat	Orifarm AS
Selexid	Pivmecillinamhydroklorid	Orifarm AS
Vermox	Mebendazol	Orifarm AS
Imatinib Accord	Imatinibmesilat	Orifarm AS
Bosentan Aurobindo	Bosentanmonohydrat	Orifarm AS
Besremi	Ropeginterferon alfa-2b	Orifarm AS
Nubeqa	Darolutamid	Orifarm AS
Saxenda	Liraglutid	Orifarm AS
Wakix	Pitolisanthydroklorid	Orifarm AS
Aduvanz	Lisdeksamfetamindimesilat	Orifarm AS
Zeposia	Ozanimodhydroklorid	Orifarm AS
Octostim	Desmopressinacetat	Orifarm AS
Erleada	Apalutamid	Orifarm AS
Vimizim	Elosulfase alfa	Orifarm AS
Cotellic	Kobimetinibhemifumarat	Orifarm AS
Vyndaqel	Tafamidismeglumin	Orifarm AS
Zejula	Niraparibtosilatmonohydrat	Orifarm AS
Harvoni	Ledipasvir, Sofosbuvir	Orifarm AS
Lorviqua	Lorlatinib	Orifarm AS
Deferasirox Orifarm	Deferasiroks	Orifarm Generics A/S
Fingolimod Orion	Fingolimodhydroklorid	Orion Corporation - Espoo

Sitagliptin/Metformin Orion	Sitagliptinhydrokloridmonohydrat, Metforminhydroklorid	Orion Corporation - Espoo
Metformin PharmConsul	Metforminhydroklorid	PharmConsul s.r.o.
Exametazime Radiopharmacy Laboratory	Eksametazim	Radiopharmacy Laboratorium Kft.
Benzylpenicillinnatrium Sandoz	Benzylpenicillinnatrium	Sandoz - København
Airbufo Forspiro	Budesonid, Formoterolfumaratdihydrat	Sandoz - København
Inzolfi	Fingolimodhydroklorid	Sandoz - København
Apixaban Sandoz	Apiksaban	Sandoz - København
Icatibant STADA	Ikatibantacetat	Stada Arzneimittel AG
Ferulinor	Lenalidomid	STADA Nordic Aps
Aitmyte	Allergen av husstøvmidd, dermatophagoides farinae, Allergen av husstøvmidd, dermatophagoides pteronyssinus	Stallergenes
Alfacalcidol Strides	Alfakalsidol	Strides Nordic ApS
Colecalciferol Strides	Kolekalsiferol	Strides Pharma (Cyprus) Limited
Azacitidin SUN	Azacitidin	Sun Pharmaceutical Ind. Europe BV
Dutasterid/Tamsulosin Teva	Dutasterid, Tamsulosinhydroklorid	Teva B.V.
Airomir	Salbutamolsulfat	Teva B.V.
Fesoterodine Teva	Fesoterodinfumarat	Teva B.V.
Fampridin Teva	Fampridin	Teva GmbH
Risperidone Teva GmbH	Risperidon	Teva GmbH
Paliperidon Teva	Paliperidonpalmitat	Teva GmbH
Treprostinil Tillomed	Treprostinil	Tillomed Pharma GmbH - Schönefeld
Trientine Tillomed Pharma GmbH	Trientindihydroklorid	Tillomed Pharma GmbH - Schönefeld
Ticagrelor Viatris	Tikagrelor	Viatris Limited
Fluconazol Vitabalans	Flukonazol	Vitabalans Oy
Qsiva	Fentermin, Topiramat	VIVUS BV
Carmustine Waymade	Karmustin	Waymade BV
Sitagliptin Zentiva	Sitagliptinhydroklorid	Zentiva k.s.
Icatibant Zentiva	Ikatibantacetat	Zentiva k.s.
Fingolimod Zentiva	Fingolimodhydroklorid	Zentiva k.s.

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 31.12.2024

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2024, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**