

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

2020

Marketing Authorisations granted in Norway 01.01.2017 - 31.12.2017 (Table 1.)
Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2020 (Table 2.)

The deadline for an exemption application is: 31.12.2020

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 01.01.2017- 31.12.2017

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Jardiance	Empagliflozin	2care4
Enstilar	Kalsipotriolmonohydrat, Betametasondipropionat	2care4
Methotrexate Accord	Metotreksat	Accord Healthcare B.V.
Atorvastatin Accord	Atorvastatin	Accord Healthcare B.V.
Lopinavir/Ritonavir Accord	Lopinavir, Ritonavir	Accord Healthcare B.V.
Idarubicin Accord	Idarubicinhydroklorid	Accord Healthcare B.V.
Pulmopresil	Sildenafil	Actavis Group PTC ehf
Ezetimib Actavis	Ezetimib	Actavis Group PTC ehf
Vasokinox	Nitrogenmonoksid	Air Liquide Santé International
Kagitz	Kvetiapinfumarat	Amneal Pharma Europe Limited, Aristo Pharma GmbH
Imatinib Aristo	Imatinib	Aristo Pharma GmbH
Lidocaine Aristo	Lidokainhydrokloridmonohydrat	Aristo Pharma GmbH
Sildenafil Amneal	Sildenafilsitrat	Aristo Pharma GmbH
Bosentan Amneal	Bosentan	Aristo Pharma GmbH
Duosol Kaliumfri	Kalsiumkloriddihydrat, Glukosemonohydrat, Magnesiumkloridheksahydrat, Natriumklorid, Natriumhydrogenkarbonat	B. Braun Avitum AG
Duosol Kalium 2 mmol/l/Duosol Kalium 4 mmol/l	Kalsiumkloriddihydrat, Glukosemonohydrat, Magnesiumkloridheksahydrat, Kaliumklorid, Natriumklorid, Natriumhydrogenkarbonat	B. Braun Avitum AG
Mustinal	Bendamustinhydroklorid	Chemi S.p.A
Relifine	Morfinhydrokloridtrihydrat	Eurocept International B.V
Filavac VHD K C+V	Kanin hemoragisk sykdom, type 2 virus (RHDV2), inaktivert, Kanin hemoragisk sykdom, type 1 virus (RHDV1), inaktivert	Filavie SAS
Lyngonia	Melbærblad	Florealis ehf.

Harpatinum	Djevelklorot	Florealis ehf.
Bicafres	Natriumhydrogenkarbonat	Fresenius Medical Care Deutschland GmbH
Oviderm	Propylenglykol	Galenica AB
Atovakon/proguanil Glenmark	Atovakvon, Proguanilhydroklorid	Glenmark Arzneimittel GmbH
Rosuvastatin Glenmark	Rosuvastatinkalsium	Glenmark Arzneimittel GmbH
Prelando	Lidokain	Grünenthal GmbH
Lonioban	Lidokain	Grünenthal GmbH
Tadalafil Krka	Tadalafil	KRKA, d.d. Novo mesto
Crusia	Enoksaparinnatrium	Laboratorios Farmaceuticos Rovi S.A
Enoxaparin Becat	Enoksaparinnatrium	Laboratorios Farmaceuticos Rovi S.A
Etonogestrel/Ethinylestradiol Leon Farma	Etonogestrel, Etinyløstradiol	Laboratorios Leon Farma, S.A.
Etonogestrel/Ethinylestradiol Chemo	Etonogestrel, Etinyløstradiol	Laboratorios Leon Farma, S.A.
Repose vet	Pentobarbitalnatrium	Le Vet Beheer B.V.
Ophtaclin vet	Klortetrasyklinhydroklorid	Le Vet Beheer B.V.
Doxybactin vet	Doksisyklinhyklat	Le Vet Beheer B.V.
Metrobactin vet	Metronidazol	Le Vet Beheer B.V.
Cefabactin vet	Cefaleksinmonohydrat	Le Vet Beheer B.V.
Tranquigel vet	Acepromazinmaleat	Le Vet Beheer B.V.
Spizobactin vet	Spiramycin, Metronidazol	Le Vet Beheer B.V.
Atorvastatin Medical Valley	Atorvastatin	Medical Valley Invest AB
Rowiren	Rosmarinolje	Medis GmbH
Solifenacin Medreich	Solifenacinsuksinat	Medreich Plc
Abakavir/Lamivudin Mylan Pharma	Abakavirsulfat, Lamivudin	Mylan AB
Erlotinib Mylan	Erlotinib	Mylan AB
Allopurinol Mylan	Allopurinol	Mylan AB
Nevirapine Mylan	Nevirapin	Mylan AB
Fibryga	Humanfibrinogen	Octapharma AB
Spiolto Respimat	Tiotropiumbromid, Olodaterol	Orifarm AS
Xoterna Breezhaler	Indakaterolmaleat, Glykopyrroniumbromid	Orifarm AS
Orfadin	Nitisinon	Orifarm AS
Atopica	Ciklosporin	Orifarm AS
Jaydess	Levonorgestrel	Orifarm AS
Orkambi	Lumakaftor, Ivakaftor	Orifarm AS
Tobi	Tobramycin	Orifarm AS
Flutiform	Flutikasonpropionat, Formoterolfumaratdihydrat	Orifarm AS
Suprane	Desfluran	Orifarm AS
Jardiance	Empagliflozin	Orifarm AS
Aclasta	Zoledonsyremonohydrat	Orifarm AS
Losec Mups	Omeprazolmagnesium	Orifarm AS
Spiriva Respimat	Tiotropiumbromid	Orifarm AS
Terbinafin Hexal	Terbinafinhydroklorid	Orifarm AS
Galvus	Vildagliptin	Orifarm AS
Xylocain	Lidokain	Orifarm AS
Persantine Retard	Dipyridamol	Orifarm AS

Incruse	Umeklidinium	Orifarm AS
Ultibro Breezhaler	Indakaterolmaleat, Glykopyrroniumbromid	Orifarm AS
Stamaril	Gulfebervirus (levende, svekket)	Orifarm AS
Persantin Retard	Dipyridamol	Orifarm AS
Eylea	Aflibercept	Orifarm AS
Fosrenol	Lantankarbonathydrat	Orifarm AS
Fosamax	Alendronatnatriumtrihydrat	Orifarm AS
Emselex	Darifenacin	Orifarm AS
Entresto	Sakubitril, Valsartan	Orifarm AS
Aldara	Imikvimod	Orifarm AS
Nicovel	Nikotin	Orifarm Generics A/S
Lercanidipine Orion	Lerkanidipinhydroklorid	Orion Corporation - Espoo
Solifenacin Orion	Solifenacinsuksinat	Orion Corporation - Espoo
Tenofovir disoproxil Orion	Tenofovirdisoproksilfumarat	Orion Corporation - Espoo
Buprenorphine Orion	Buprenorfin	Orion Corporation - Espoo
Kloramfenikol Pharmathen	Kloramfenikol	Pharmathen S.A
Ursosan	Ursodeoksykolsyre	Pro.Med.CS
Noresmea	Østradiolhemihydrat, Noretisteronacetat	Sandoz - København
Solvetta	Etonogestrel, Etinyløstradiol	Sandoz - København
Kaliumklorid Sandoz	Kaliumklorid	Sandoz - København
Airflusal Sprayhaler	Salmeterolxinafoat, Flutikasonpropionat	Sandoz - København
Triaxis	Difteritoksoid, Tetanustoksoid, Pertussistoksoid, Filamentøst hemagglutinin, Pertaktin (kikhosteantigen), Fimbriae type 2 og 3	Sanofi Pasteur Europe
Rosuvastatin Teva	Rosuvastatin	Teva B.V.
Everolimus Teva	Everolimus	Teva Sweden AB
Entecavir Teva B.V.	Entekavir	Teva Sweden AB
Entecavir Teva	Entekavirmonohydrat	Teva Sweden AB
Entecavir Teva Pharma	Entekavir	Teva Sweden AB
Kolkisin Tiofarma	Kolkisin	Tiofarma B.V.
Pemetrexed Norameda	Pemetrekseddikalium	UAB Norameda
Ferofix	Jern(III) hydroksid polymaltosekompleks	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.
Ubroseal vet	Vismutsubnitrat, tungt	Univet Ltd
Ceftiocyl vet	Ceftiofur	VETOQUINOL SCANDINAVIA AB
CANIGEN L	Leptospira interrogans serogruppe Canicola serovar Canicola, inaktivert, Leptospira interrogans serogruppe Icterohaemorrhagiae serovar Icterohaemorrhagiae, inaktivert	VIRBAC
CANIGEN Pi/L	Hundeparainfluenzavirus (CPIV), Leptospira interrogans serogruppe Canicola serovar Canicola, inaktivert, Leptospira interrogans serogruppe Icterohaemorrhagiae	VIRBAC

	serovar Icterohaemorrhagiae, inaktivert	
Suvaxyn Parvo-E Amphigen	Porcint parvovirus, inaktivert, Erysipelotrix rhusiopathiae serotype 2, inaktivert	Zoetis Finland Oy

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2020

Product name	Active substance(s)	Marketing Authorisation Holders (MAHs)
Mometasone Actavis	Mometasonfuroatmonohydrat	Actavis Group PTC ehf
Iluvien	Fluocinolonacetamid	Alimera Sciences Limited
Docetaxel Amring	Docetaxel	Amring S.A.S.
Carvedilol Aristo	Karvedilol	Aristo Pharma GmbH
Stromolol	Bisoprolol	Aristo Pharma GmbH
Oroxine	Levotyrosin	Aspen Pharma Trading Limited
Fluconazol Baxter	Flukonazol	Baxter Holding B.V.
Adaxio Vet	Klorhexidin, mikonazol	Ceva Santé Animale
Dutasteride Cipla	Dutasterid	Cipla Europe NV
Albumin Behring	Humanalbumin	CSL Behring GmbH
Xolipos	Zolpidemtartrat	Dune Medicare ApS
Hydroxyzine EQL Pharma	Hydroksyzinhydroklorid	EQL Pharma AB
Arimidex	Anastrozol	Farmagon
Brilique	Tikagrelor	Farmagon
Lodoz	Bisoprolol, hydroklortiazid	Farmagon
Fluorette	Natriumfluorid	Fertin Pharma A/S
Priorix Tetra	Meslingvirus, rubellavirus, parotittvirus, Varicella zoster virus	GlaxoSmithKline Biologicals S.A.
Carprofen Krka	Karprofen	KRKA, d.d. Novo mesto
Drosetil 28	Etinyløstradiol, drospirenon	Laboratorios Leon Farma, S.A.
Axibal	Ibandronsyre	Laboratorios Liconsa S.A.
Bonefurbit	Ibandronsyre	Laboratorios Liconsa S.A.
Ibandronsyre Liconsa	Ibandronsyre	Laboratorios Liconsa S.A.
Kefort	Ibandronsyre	Laboratorios Liconsa S.A.
Licobondrat	Ibandronsyre	Laboratorios Liconsa S.A.
Nucodran	Ibandronsyre	Laboratorios Liconsa S.A.
Ratiban	Ibandronsyre	Laboratorios Liconsa S.A.
Vinodran	Ibandronsyre	Laboratorios Liconsa S.A.
Pepciduo	Famotidin, Magnesiumhydroksid, Kalsiumkarbonat	McNeil Sweden AB
Asolvid	Losartankalium, hydroklortiazid.	Mylan AB
Oxaplamyl	Oksaliplatin	Mylan Ireland Limited
Pantoprazole Mylan	Pantoprazol	Mylan Ireland Limited
Artelac	Hypromellose	Orifarm AS
Desferal	Deferoksaminmesilat	Orifarm AS
Inovelon	Rufinamid	Orifarm AS
Lamictal	Lamotrigin	Orifarm AS
Meropur	Menotropin, humant	Orifarm AS
Nevanac	Nepafenak	Orifarm AS
Nimenrix	Vaksine mot meningokokkinfeksjon gruppe A, C, W-135 og Y (konjugert)	Orifarm AS

Rebetol	Ribavirin	Orifarm AS
ReoPro	Abciximab	Orifarm AS
Vidaza	Azacitidin	Orifarm AS
Vimovo	Naproxen, esomeprazol	Orifarm AS
Xarelto	Rivaroksaban	Orifarm AS
Xgeva	Denosumab	Orifarm AS
Xiapex	Kollagenase clostridium histolyticum	Orifarm AS
Zanedip	Lerkanidipinhydroklorid	Orifarm AS
Cetirizin Orifarm	Cetirizinhydroklorid	Orifarm Generics
Mometason Orion	Mometasonfuroat	Orion Corporation - Espoo
Midazolam Orpha	Midazolam maleat	Orpha-Devel Handels und Vertriebs GmbH
Rokuroniumbromid Pfizer	Rokuroniumbromid	Pfizer
Meropenem	Meropenem trihydrat	PFIZER AS
Montelukast Sandoz	Montelukast	Sandoz - København
Zoledronsyre Seacross	Zoledronsyre	Seacross Pharmaceuticals Limited
Serelys	Tørret ekstrakt (PI 82) av pollen fra Secale cereale L. (rug), Dactylis glomerata L. (hundegras), Zea mays L. (mais), Pinus sylvestris L. (furu) og fruktblad fra Zea mays L. (mais).	Serelys Pharma Netherlands B.V.
Latanoprost Sifi	Latanoprost	SIFI SpA
Venastat	Hestekastanjefrø	Temmler Pharma GmbH
Valganciclovir Teva	Valganciklovirhydroklorid	Teva Pharma B.V
Ciqorin	Ciklosporin	Teva Pharma B.V
Neoprnil	Eprinomektin	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 31.12.2020

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2020, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**