

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

2018

Marketing Authorisations granted in Norway 01.01.2015 - 31.12.2015 (Table 1.)

Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2018 (Table 2.)

The deadline for an exemption application is: 31.12.2018

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 01.01.2015 - 31.12.2015

Product name	Marketing Authorisation Holders (MAHs)
Phenergan	2care4
Duloxetine Accord	Accord Healthcare
Rosuvastatin Accord	Accord Healthcare
Mykofenolsyre Accord	Accord Healthcare
Brinzolamide Actavis	Actavis Group
Vancomycin Actavis	Actavis Group
Flynise	Actavis Group
Rasagilin Actavis	Actavis Group
Namaxir	Actavis Group
Dutasteride Actavis	Actavis Group
Emerpand	Actavis Group
Aritavi	Actavis Group
Bosentan Actavis	Actavis Group
Nerozila	Actavis Group
Bendamustin Actavis	Actavis Group
Rivendra	Actavis Group
Voriconazole Actavis	Actavis Group
Sturiban	Actavis Group
Ipandin	Actavis Group
Monovo	Almirall Hermal GmbH
Bupivacaine Alternova	Alternova
Aripiprazole Amneal	Amneal Pharma Europe
Rasagiline Amneal	Amneal Pharma Europe
Animed vet	aniMedica GmbH
Bosentan Aurobindo	Aurobindo Pharma (Malta)
Yanimo Respimat	Boehringer Ingelheim International
Srivasso Genahaler	Boehringer Ingelheim International
Zodon vet	Ceva Santé Animale

Vetmast	Divasa-Farmavic S.A.
Permacyl	Divasa-Farmavic S.A.
Ipravent	ELC Group s.r.o
Lisinopril EssPharm	Essential Pharmaceuticals Ltd.
Diza	Exeltis Healthcare S.L.
Vitaros	Ferring Legemidler AS
Bovigen RCE vet	Forte Healthcare Limited
Adenosin Fresenius Kabi	FRESENIUS KABI NORGE AS
Voriconazole Fresenius Kabi	FRESENIUS KABI NORGE AS
Geloplasma	Fresenius Kabi Norge
Lenzetto	Gedeon Richter
Yana	Heaton k.s
Ebelya	Heaton k.s
Bortega	Heaton k.s
Cinavi	Helm AG
Ziqamil vet	KRKA, d.d. Novo mesto
Linezolid Krka	KRKA, d.d. Novo mesto
Bloxazoc	KRKA, d.d. Novo mesto
Pregabalin Krka	KRKA, d.d. Novo mesto
Pemetrexed Reig Jofre	Laboratorio Reig Jofre
Amoxibactin Vet	Le Vet Beheer
Implicor	Les Laboratoires Servier
Bortezomib Logenex	Logenex Pharm GmbH
Bendamustin medac	Medac - Gesellschaft für klinische Spezialpräparate
Aripiprazole Medical Valley	Medical Valley Invest AB
Eurican L3	Merial Norden
Eurican DHPPi2-L3	Merial Norden
Sevelamer Mylan	Mylan AB
Aldemyl	Mylan AB
Menjugate	Novartis Vaccines and Diagnostics S.r.l
Nicabate	Omega Pharma Nordic AB
Profender	Orifarm AS
Enbrel	Orifarm AS
Lescol MR	Orifarm AS
Taflotan	Orifarm AS
Zaditen	Orifarm AS
Cancidas	Orifarm AS
Vigantol	Orifarm AS
Orfiril long	Orifarm AS
Javlor	Orifarm AS
Forsteo	Orifarm AS
Estalis	Orifarm AS

Mezavant	Orifarm AS
Zinacef	Orifarm AS
Benlysta	Orifarm AS
Ferinject	Orifarm AS
Parvoruvac	Orifarm AS
Epiduo	Orifarm AS
Forxiga	Orifarm AS
Diovan	Orifarm AS
Voltaren	Orifarm AS
Olysio	Orifarm AS
Frivelle	Orifarm Generics
Olanzapin Orion	Orion Corporation
Desfluran Piramal	Piramal Healthcare UK Limited
Solifenacin Sandoz	Sandoz - København
Imatinib Sandoz	Sandoz - København
Delamonie	Sandoz - København
Fulvestrant Sandoz	Sandoz - København
Rigmin	Sandoz - København
Bisolaclar	SANOFI-AVENTIS NORGE AS
Crealb	Sanquin Plasma Products B.V.
Jiskyn	Synthon BV
Atazanavir Teva	Teva Sweden AB
Aripiprazole Teva	Teva Sweden AB
Tadalafil Teva	Teva Sweden AB
Efficanix	VIRBAC
Alverin	Zoetis Finland Oy
Ketastesic Vet	Zoetis Finland Oy

Table 2 - Marketing Authorisations granted 3 years exemption for sunset clause until 31.12.2018

Product name	Marketing Authorisation Holders (MAHs)
Irbesartan Accord	Accord Healthcare
Montelukast Accord	Accord Healthcare
Fluvastatin Accord	Accord Healthcare
Losartan Actavis	Actavis Group
Buprenorphine Actavis	Actavis Group
Losartan/Hydroklortiazid Actavis	Actavis Group
Rosuvastatin Actavis	Actavis Group
Tolterodin Actavis	Actavis Group
Atorvastatin Actavis	Actavis Group
Mirtazapin Actavis	Actavis Group
Veropol	AJ Vaccines
diTekiBooster	AJ Vaccines
Afluria	bioCLS GmbH

Ovarelin	Ceva Santé Animale
Fludarabin Ebewe	EBEWE Pharma
Epirubicin Ebewe	EBEWE Pharma
Zoledronsyre Gedeon Richter	Gedeon Richter
Zoledronsyre Richter	Gedeon Richter
Infanrix Polio	GlaxoSmithKline
Paracetamol/Phenylephrine Hermes	Hermes Arzneimittel
Flarin	Infirst Healthcare
Porcilis M1 ID	Intervet International
Erwinase	Jazz Pharmaceuticals France SAS
Lymecycline Kinedexe	Kinedexe UK Limited
Mirtin	KRKA Sverige AB
Montelukast Krka	KRKA Sverige AB
Quetiapine Krka	KRKA Sverige AB
Flexove	Laboratoires Expanscience
Iren/Iren 28	Laboratorios Leon Farma,
Ospen	Laboratorios Leon Farma,
Rosal/ Rosal 28	Laboratorios Leon Farma,
Naiwanel/ Naiwanel 28	MEDICAL VALLEY
Ospen 28	MEDICAL VALLEY
Rosal	MEDICAL VALLEY
Amoxicillin MIP Pharma	MIP Pharma
Irbesartan Mylan	Mylan AB
Tolterodin Mylan	Mylan AB
Losartan Mylan	Mylan AB
Fentanyl Mylan	Mylan AB
Dolatramyl	Mylan AB
Valaciclovir Mylan	Mylan AB
Vancomycin Mylan	Mylan Hospital AS
Natriumklorid Noridem	Noridem Enterprises Ltd.
Sterilt vann Noridem	Noridem Enterprises Ltd.
Kaliumklorid Noridem	Noridem Enterprises Ltd.
Livostin	Orifarm AS
Atarax	Orifarm AS
Clindamycin Orifarm	Orifarm Generics
Rizatriptan Orifarm	Orifarm Generics
Alfacalcidol Orifarm	Orifarm Generics
Diclofenackalium Orifarm	Orifarm Generics
Ketipinor	Orion Corporation
Ropinirol Orion	Orion Corporation
Alpha Marine Vibject	Pharmaq AS
Alpha Marine Vibrio	Pharmaq AS
Latanoprost ratiopharm	Ratiopharm GmbH
Levetiracetam Sandoz	Sandoz - København
Calima	Sandoz - København

Calima 28	Sandoz - København
Tolterodine Sandoz	Sandoz - København
Zoledronsyre Sandoz	Sandoz - København
Elyria	Sandoz - København
Elyria 28	Sandoz - København
Finasterid Sandoz	Sandoz - København
Piperacillin/Tazobactam Sandoz	Sandoz - København
Mirtazapin Sandoz	Sandoz - København
Topiramate Sandoz	Sandoz - København
Pentavac	Sanofi Pasteur Europe
Viatim	Sanofi Pasteur Europe
Songha Natt	Soho Flordis UK Ltd.
Terlipressin SUN	Sun Pharmaceutical - Nederland
Dretine/Dretine 28	Teva Sweden AB
Dretinelle/Dretinelle 28	Teva Sweden AB
Varena/Varena 28	Teva Sweden AB
Varenelle/Varenelle 28	Teva Sweden AB
Uvadex	Therakos (UK), Limited
Fenecin	Weifa AS

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 31.12.2018.

If no written objections to the notice or exemption application(s) are submitted by the deadline 31.12.2018, the decision of cessation of the marketing authorization will come in to force by immediate effect and **without any further confirmation to the MAH.**