Nye legemidler som ikke har markedsføringstillatelse

For legemidler oppført på listen gjelder retningslinjens vilkår <u>uavhengig av indikasjon for bruken.</u>

Oppdatert: 07.08.2018

Reduction of renal radiation exposure during Peptide-Receptor Radionuclide Therapy (PRRT) with lutetium (177Lu) arginine hydrochloride Therapy (PRRT) with lutetium (177Lu) oxodotreotide Enasidenib (AML) treatment of acute myeloid leukaemia (AML) treatment of hypotension in adults with distributive or vasodilatory shock who remain hypotensive despite fluid and vasopressor therapy Angiotensin ii Treatment of psoriasis in adults Treatment of mild to moderate atopic dermatitis Treatment of faulte Bacterial Skin and Skin Structure Infection (ABSSSI) in adults Delafloxacin Axalimogene filolisbac Treatment of adults with phenylketonuria (PKU) who have inadequate blood phenylalanine control Pegvaliase Monotherapy, indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma Cemiplimab Treatment and prophylaxis of bleeding in patients with haemophilia A Turoctocog alfa pegol Glutamine Treatment of sickle cell disease First-line treatment of sickle cell disease First-line treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating mutations, mar.18 Trientine dihydrochloride Treatment of myotrophic lateral	Oppdatert: 07.08.2018			
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Selumetinib Neurofibromatosis mar.18 Treatment of amyotrophic lateral	Trientine dihydrochloride		х	mar.18
Treatment of amyotrophic lateral	Selumetinib			
		Treatment of amyotrophic lateral		
	Masitinib			mar.18

Avapritinib	Treatment of mastocytosis and GIST		mar.18
patasertib	Treatment of breastcancer		mar.18
	Treatment of non- small cell lungcancer		
	(NSCLC) and glioblastoma		
Veliparib			mar.18
	Treatment of breastcancer and		
Talazoparib	prostatecancer		mar.18
	Treatment of non-hodgkin lymphoma		
Copanlisib			mar.18
	Treatment of acute myeloid leukaemia		
Enasidenib			mar.18
Acalabrutinib	Treatment of mantel cell lymphoma		mar.18
	Conditioning treatment prior to		
	allogeneic haematopoietic stem cell		
	transplantation (alloHSCT)		
Treosulfan	transplantation (alloHSCT)	X	mar.18
	Prevention of major cardiovascular		
Canakinumab	events		mar.18
Lusutrombopag	Treatment of thrombocytopenia		mar.18
	Treatment of adult patients with		
	anaplastic lymphoma kinase (ALK)-		
	positive advanced non-small cell lung		
Lorlatinib	cancer (NSCLC)		mar.18
	Treatment of acute lymphoblastic		
Asparaginase	leukaemia	Х	mar.18
	Adjunctive therapy of seizures associated		
	with Lennox-Gastaut syndrome (LGS) or		
	Dravet syndrome (DS),		
Cannabidiol		X	mar.18
	Prevention of episodic and chronic		
Fremanezumab	migraine		mar.18
	Avatrombopag is indicated for the		
	treatment of thrombocytopenia in adult		
	patients with chronic liver disease who		
	are scheduled to undergo a procedure.		
Avatrompag Maleat			mar.18
	Routine prevention of angioedema		
	attacks and the control of symptoms of		
	hereditary angioedema (HAE) in patients		
Lanadelumab	aged 12 years and older	Х	feb.18
	Metastatic Cutaneous Squamous Cell		
	Carcinoma (CSCC) indicated for the		
	treatment of patients with metastatic		
	cutaneous squamous cell carcinoma		
	(mCSCC), or with locally advanced		
	cutaneous squamous cell carcinoma		
	(laCSCC) who are not candidates for		
Regn2810	surgery		feb.18

	T T		
	Small cell lung cancer (SCLC) -		
	maintenance following first-line platinum		
Rovalpituzumab tesirine	chemotherapy		jan.18
Edaravone	Amyotrophic lateral sclerosis (ALS)		jan.18
	Treatment of hereditary transthyretin-		
Patisiran	mediated amyloidosis	x	jan.18
	Induction of response in adult patients		
	with granulomatosis with polyangiitis		
	(Wegener's) (GPA) or microscopic		
Avacopan	polyangiitis (MPA	x	jan.18
Romosozumab	Treatment of osteoporosis		jan.18
	Intended for the treatment of adult men		
	with NM-CRPC who are at high risk of		
	developing metastatic disease.		
Apalutamide			jan.18
-	Treatment of adults infected with HIV-1		,
	without past or present evidence of viral		
	resistance to treatment of adults infected		
	with HIV-1 without past or present		
	evidence of viral resistance to doravirine,		
	evidence of viral resistance to doravirine,		
Doravirine			des.17
Doraviiiie	Treatment of adults infected with HIV-1		463.17
	without past or present evidence of viral		
Doravirine / lamivudine /	resistance to doravirine, lamivudine, or		
tenofovir disoproxil	tenofovir		des.17
Galcanezumab	Prophylaxis of migraine		des.17
Galcariezurrab	Treatment of transthyretin amyloidosis		ue3.17
Inotersen	(hATTR)	v	des.17
motersen	Diagnosis of Adult growth hormone	Х	ues.17
Macimorelin			des.17
Macimoreilli	deficiency (AGHD)		ues.17
Lluman fibrinagan / buman	To support the endogenous clotting		
Human fibrinogen / human	process and increase of haemostasis in		dos 17
thrombin	surgical procedures		des.17
Barras litera (la la calita	Treatment of adults with high-risk acute		.147
Daunorubicin / cytarabine	myeloid leukaemia (AML)	X	des.17
	Treatment of acute radiation syndrome		
Entolimod		Х	nov.17
	Treatment of cutaneous T-cell lymphoma		
Mogamulizumab		Х	nov.17
	Treatment of locally advanced,		
	unresectable non-small cell lung cancer		
	(NSCLC).		
Durvalumab	Urotelial cancer (mars 2018)		okt.17
	Treatment and prophylaxis of		
Damoctocog alfa pegol	haemophilia A	Х	okt.17

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F508del mutation in the CFTR gene, and a		
12 years and older who have at least one		
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vertical lines between the eyebrows		jul.17
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Tamparani impravament in the		Jui.17
		jul.17
Temporary improvement in the		,
appearance of moderate to severe		
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Treatment of infections		jul.17
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The treatment or patients with CF aged		
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Intended for the treatment of adult		
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patients with diffuse large B-ceil		
lymphoma (DLRCL) who have not		
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responded to their prior therapy, or have		
had disease progression after autologous		
stem cell transplant (ASCT)		
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Indicated for prophylaxis of migraine in		
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Treatment of von Willebrand Disease		
(VWD)		47
1////////	Х	jun.17
	appearance of moderate to severe vertical lines between the eyebrows Treatment of infections The treatment or patients with CF aged 12 years and older who have at least one F508del mutation in the CFTR gene, and a second mutation that is responsive to tezacaftor/ivacaftor Intended for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) who have not responded to their prior therapy, or have had disease progression after autologous stem cell transplant (ASCT) Indicated for prophylaxis of migraine in adults Treatment of von Willebrand Disease	appearance of moderate to severe vertical lines between the eyebrows Treatment of infections The treatment or patients with CF aged 12 years and older who have at least one F508del mutation in the CFTR gene, and a second mutation that is responsive to tezacaftor/ivacaftor Intended for the treatment of adult patients with diffuse large B-cell lymphoma (DLBCL) who have not responded to their prior therapy, or have had disease progression after autologous stem cell transplant (ASCT) X Indicated for prophylaxis of migraine in adults Treatment of von Willebrand Disease

* Se informasjon om COMP (komiteen for legemidler mot sjeldne sykdommer) på www.legemiddelverket.no

**Fotnote/ Masitinib:

http://www.ema.europa.eu/do cs/en_GB/document_library/Su mmary_of_opinion_-_Initial_authorisation/human/0 04398/WC500247742.pdf