

FINISHED DOSAGE FORMS

Flavine supports you in the following areas:

- Procurement of licenses and active marketing authorizations.
- Co-development of dossiers for niche products and innovative pharmaceutical forms with European partners (starting from API development to finished product).
- In- and out-licensing of generics, innovative pharmaceutical technologies and novel products.
- Contract manufacturing services in Europe and Asia.

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FINISHED DOSAGE FORM / DOSSIERS



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PRODUCT	TRADE NAME	GALENIC FORM	DOSAGE STRENGTH	EUGMP FOR PRODUCT (Y/N)	THERAPEUTIC USE	INDICATION	THERAPEUTIC CATEGORY COMPETITORS	DOSSIER READY (Y/N)	MA EXPECTED/GRANTED
Acarbose	Glucobay	tablet	50, 100 mg	Y	Antidiabetic	Diabetes mellitus type 2	Miglitol	Y	Nationally approved
Acetylcysteine	Mentopin	tablet	1200 mg	Y	Antidiuretic, Mucolytic	Acetaminophen overdose, Asthmatic bronchitis	Desmopressin acetate	Y	Nationally approved
Amiodarone	Cardarone	injection	150 mg/3 ml	Y	Antiarrhythmic, Antianginal	Ventricular arrhythmia	Timolol, Lidocaine	Y	Nationally approved
Amiodarone	Cardarone	tablet	200 mg	Y	Antiarrhythmic, Antianginal	Ventricular arrhythmia	Timolol, Lidocaine	Y	Nationally approved
Azithromycin Dihydrate*	Zithromax	tablet*	250/500 mg*	Y	Antibacterial	Chronic pulmonary disease	Cefuroxime sodium, Erythromycin	Y	Nationally approved
Ciprofloxacin	Ciprobay	mono dose vial	1 mg/0,5 ml ophthalmic solution	Y	Antibacterial	Quinolone antibacterial, Bacterial conjunctivitis, Infection of skin, Otitis externa	Gatifloxacin, Gemifloxacin mesylate, Linezolid	Y	Nationally approved
Clopidogrel bisulfate	Plavix	tablet (film coated)	75 mg	Y	Antithrombotic	Thrombosis orohxialis	Bivalirudin, Acetaminophen	Y	DCP ongoing
Donepezil	Aricept	tablet	5, 10 mg	MHRA	Nootropic	Alzheimer's disease - Dementia	Rivastigmine	Y	DCP approved by Q4/2011
Dorzolamide*	Trusopt	eye drops*	2 %/5 ml*	Y	Antiglaucoma, Carbonic Anhydrase Inhibitor	Glaucoma	Bimatoprost, Latanoprost, Travoprost, Brinzolamide	Y	DCP approved
Escitalopram*	Cipralext	tablet*	5, 10, 20 mg*	MHRA	Antidepressant	Anxiety disorder, Depressive disorder	Aprepitant, Desvenlafaxine succinate monohydrate, Duloxetine hydrochloride	Y	DCP approved by Q1/2011
Fluconazole*	Diflucan	capsule*	50, 100, 150, 200 mg*	Y	Antifungal	Candidiasis prophylaxis, Cryptococcal meningitis	Posaconazole	Y	Nationally approved
Fluconazole*	Diflucan	oral solution*	50 mg/5 ml, 200 mg/5 ml*	Y	Antifungal	Candidiasis prophylaxis, Cryptococcal meningitis	Posaconazole	Y	Nationally approved
Fludarabine phosphate inj	Fludara	vial	50 mg powder for injection	Y	Antineoplastic	B-cell chronic lymphocytic leukemia	Bendamustine hydrochloride, Capecitabine, Gemcitabine hydrochloride, Imatinib mesylate, Mycophenolic acid, Pemetrexed disodium, Topotecan hydrochloride	Y	Nationally approved by Aug 2011
Fosfomycin Trometamol	Monuril	sachet	3 gm	Y	Antibacterial	Urinary tract infection	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	Nationally approved
Iloprost	Ilomedine	vial	0,5 ml/0,05 mg	Y	Prostaglandin	Pulmonary hypertensive arterial disease	Bivalirudin	Y	Nationally approved by Q3/2011
Imipenem/Cilastatin	Tienam	vial	250/250 mg & 500/500 mg powder for IV injection	Y	Antibacterial	Lower respiratory tract infections, Urinary tract infections, Intra-abdominal infections, Gynecologic infections, Skin infections	Ertapenem, Biapenem, Feropenem	Y	Nationally approved by Sep 2011
Irbesartan*	Aprovel	tablet*	75, 150, 300 mg*	Y	Antihypertensive	Diabetic nephropathy, Hypertension	Candesartan cilexetil, Olmesartan medoxomil, Telmisartan, Valsartan,	Y	DCP approved by Q3/2012
Latanoprost	Xalatan	eye drops	0.005% (50 µg/mL)	Y	Prostaglandin	Ocular hypertension	Bimatoprost, Travoprost, Brinzolamide	Y	Nationally approved
Latanoprost/Timolol	Xalacom	eye drops	2,5 ml eye drops - 0,05 mg/ml latanoprost / 5 mg/ml Timolol	Y	Prostaglandin	Ocular hypertension	Carvedilol, Nebivolol hydrochloride	Q3/2011	DCP approved by Q4/2012
Levofloxacin*	Tavanic	tablet*	250, 500 mg*	MHRA	Antibacterial	Bacterial conjunctivitis, Chronic bronchitis	Doripenem, Moxifloxacin hydrochloride	Y	DCP approved by Q1/2011
Meropenem	Meropen	vial	500 and 1000 mg powder for injection	Y	Antibacterial	Bacterial meningitis, Infection of skin, Infectious disease of abdomen	Ertapenem, Pimecrolimus, Tigecycline	Y	Nationally approved by Q3/2011
Montelukast*	Singulair	tablet (film coated and chewable)*	10 mg, 4 & 5 mg*	Y	Antiinflammatory, Antihistaminic	Asthma	Desloratadine, Olopatadine hydrochloride	Y	DCP approved by Q1/2011
Nitroglycerin	Minitran	patch	5, 10, 15 mg available in package of 7, 15, and 30 patches.	Y	Vasodilator (Coronary) Antianginal	Angina pectoris, Hypertension	Eptifibatid, Ranolazine, Timolol	Y	Nationally approved
Olanzapine*	Zyprexa	tablet (film coated)*	2,5, 5, 7,5, 10, 15 & 20 mg*	Y	Antipsychotic	Schizophrenia, Bipolar I disorder, Bipolar I mania, Depression	Aripiprazole, Olanzapine pamoate, Paliperidone, Quetiapine fumarate	Y	DCP approved by Q2/2011
Olanzapine*	Zyprexa	tablet (orodispersible)*	5, 10, 15 & 20 mg*	Y	Antipsychotic	Schizophrenia, Bipolar I disorder, Bipolar I mania, Depression	Aripiprazole, Olanzapine pamoate, Paliperidone, Quetiapine fumarate	Y	DCP approved by Q2/2011
Quetiapine hemifumarate*	Seroquel	tablet*	25, 100, 200, 300 mg*	Y	Antipsychotic	Schizophrenia, Bipolar I disorder, Bipolar I mania, Bipolar II depression	Olanzapine, Olanzapine pamoate, Paliperidone, Ziprasidone hydrochloride	Y	DCP approved by Q1/2012
Rifaximin	Normix	tablet	200 mg	Y	Antibacterial	Travelers' diarrhea	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	Nationally approved
Risperidone*	Risperdal	tablet*	0,5, 1, 2, 3, 4, 6 mg*	Y	Antipsychotic	Schizophrenia, Bipolar disorder, Irritability in children with autism	Aripiprazole, Olanzapine, Olanzapine pamoate, Paliperidone, Quetiapine fumarate	Y	MRP approved
Spiramycin Metronidazole bi	Rodogyl	tablet	1,5 MIU - 250 mg	Y	Antibacterial	Acute, chronic and recurring stomatological infections	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	DCP approved
Spiramycin Metronidazole bi*	Rodogyl	dispersible tablet*	1,5 MIU - 250 mg*	Y	Antibacterial	Acute, chronic and recurring stomatological infections	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	DCP approved
Spiramycin Metronidazole mono*	Rodogyl	dispersible tablet*	0,75 MIU - 125 mg*	Y	Antibacterial	Acute, chronic and recurring stomatological infections	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	DCP approved
Spiramycin*	Rovamycine	tablet*	1,5 MIU, 3 MIU*	Y	Antibacterial	Toxoplasmosis in pregnant women	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	filing upon customer interest
Spiramycin*	Rovamycine	dispersible tablet*	1,5 MIU, 3 MIU*	Y	Antibacterial	Toxoplasmosis in pregnant women	Ertapenem sodium, Pimecrolimus, Tigecycline	Y	filing upon customer interest
Tramadol - Paracetamol	Zaldiar	tablet	37,5 mg - 325 mg	Y	Analgesic	Short-term pain management	Pregabalin	Y	DCP approved by Q2/2011
Trimetazidine	Vastarel MR	tablet	35 mg	Y	Antianginal	Angina pectoris, Hypertension	Eptifibatid, Ranolazine	Y	Nationally approved
Valsartan*	Diovan	film coated tablet*	40, 80, 160, 320 mg*	Y	Antihypertensive	High blood pressure, Congestive heart failure	Candesartan cilexetil Irbesartan, Olmesartan medoxomil, Telmisartan	Y	DCP approved by Q4/2011

* own, proprietary technology – patented, non infringing

** available in Scandinavian, Iberian and non EU countries, UK

Disclaimer

Some of the products listed are currently under development and therefore pertinent information may not be available at this time.

Any product listed which is covered under current patents is available only for use reasonably related to the development and submission of information to the relevant Health Authorities (including the US FDA) to the extent permitted under applicable laws regulating the manufacture, use and sale of Active Pharmaceutical Ingredients and/or their intermediates.

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PRODUCT	TRADE NAME	GALENIC FORM	DOSAGE STRENGTH	EUGMP FOR PRODUCT (Y/N)	THERAPEUTIC USE	INDICATION	THERAPEUTIC CATEGORY COMPETITORS	NR/MRP/DCP *	DOSSIER READY (Y/N)	Market Authori. in EU active (Y/N)
Artificial tears	ViscoFresh	mono dose vial	-	Y	Relief from dry eye symptoms	N/A	N/A	N/A	in dev. (expected in June 2011)	N
Bosentan*	Tracleer	tablet (extended release)*	62.5, 125 mg*	pending*; MHRA by 3/2011	Antihypertensive	Pulmonary hypertension	Alfuzosin hydrochloride, Candesartan cilexetil, Irbesartan, Sildenafil citrate, Valsartan	N/A	Early dev.	N/A
Bosentan	Tracleer	tablet	62.5, 125 mg	Y	Antihypertensive	Pulmonary hypertension	Alfuzosin hydrochloride, Candesartan cilexetil, Irbesartan, Sildenafil citrate, Valsartan	N/A	in dev. (expected in Q2/2012)	N/A
Brinzolamide	Azopt	ophthalmic suspension	1%	Y	Antiglaucoma	Raised intraocular pressure	Bimatoprost, Latanoprost, Travoprost	N/A	pending	N/A
Desloratadine	Aerius, Clarinex	tablet	5 mg	Y	Antihistaminic	Chronic idiopathic urticaria, Perennial allergic rhinitis, Seasonal allergic rhinitis	Olopatadine hydrochloride	N/A	in dev. (expected in Q1/2011)	N/A
Desloratadine	Aerius, Clarinex	syrup	0,5 mg/ml	Y	Antihistaminic	Chronic idiopathic urticaria, Perennial allergic rhinitis, Seasonal allergic rhinitis	Olopatadine hydrochloride	N/A	in dev. (expected in Q3/2011)	N/A
Duloxetine*	Cymbalta, Ariclaam, Xeristar, Yentreve	capsule*	20,30,60 mg	pending; MHRA by 3/2011	Antidepressant	Diabetic peripheral neuropathy, Fibromyalgia, Generalized anxiety disorder, Major depressive disorder	Aprepitant, Desvenlafaxine succinate monohydrate, Duloxetine hydrochloride	N/A	N	Filed in US in Sep 2010
Entacapone*	Comtess	tablet*	25, 100, 125, 200 mg*	MHRA	Antiparkinsonian	Parkinson's disease	Apomorphine hydrochloride, Rasagiline mesylate	N/A	in dev. (expected by Q1/2012)	N/A
Entacapone / Levodopa / Carbidopa*	Stalevo	tablet*	200/12.5/50 mg, 200/25/100 mg, 200/37.5/150 mg, 200/50/200 mg*	Y	Antiparkinsonian	Parkinson's disease	Apomorphine hydrochloride, Entacapone, Rasagiline mesylate	N/A	in dev. (expected in Q4/2012)	N/A
Fludarabine phosphate oral*	Fludara	hard gelatine capsule*	10 mg*	Y	Antineoplastic	B-cell chronic lymphocytic leukemia	Bendamustine hydrochloride, Bexarotene, Capecitabine, Gemcitabine hydrochloride, Mycophenolic acid, Pemetrexed disodium	N/A	Q3/2011	expected in Q3/2012
Irbesartan/HCTZ	Aprovel, Coaprovel	tablet	150/12.5 mg, 300/12.5 mg, 300/25 mg	Y	Antihypertensive	Hypertension	Candesartan cilexetil, Irbesartan, Olmesartan medoxomil, Telmisartan, Valsartan	N/A	Y	expected in Q3/2011
Memantine	Axura	tablet	10, 20 mg	Y	Nootropic	Alzheimer's disease	Entacapone, Rasagiline mesylate	N/A	in dev. (Dossier expected in Q2/2011)	N/A
Paliperidone*	Invega	tablet (extended release)*	3, 6, 9 mg*	Y	Antipsychotic	Schizoaffective disorder, Schizophrenia	Olanzapine, Quetiapine fumarate, Ziprasidone hydrochloride	N/A	Q2/2014	in dev. (expected Q3/2015)
Pregabalin	Lyrica	capsule	25, 50, 75, 100, 150, 200, 225, 300 mg	Y	Anticonvulsant for neuropathic pain, Fibromyalgia, Partial seizure, Postherpetic neuralgia	Diabetic peripheral neuropathy, Fibromyalgia, Partial seizure, Postherpetic neuralgia	Acetaminophen, Tramadol hydrochloride	N/A	in dev. (Dossier expected Q2/2013)	expected Q3/2014
Travoprost	Travatan	ophthalmic solution	0,004%	Y	Antiglaucoma	Raised intraocular pressure	Bimatoprost, Latanoprost	N/A	Q4/2011	expected Q4/2012
Travoprost/Timolol	Duotrav	ophthalmic solution	0,004 %/0,5 %	Y	Antiglaucoma, Antihypertensive, Antianginal	Raised intraocular pressure, Hypertension	Nebivolol hydrochloride	N/A	Q4/2011	expected Q4/2012
Valsartan+HCTZ	Diovan, Diovan Plus	tablet	80 mg/12.5 mg, 160 mg/25 mg	MHRA	Antihypertensive	Hypertension	Candesartan cilexetil, Irbesartan, Olmesartan medoxomil, Telmisartan, Valsartan	N/A	in dev. (Dossier expected in Q1/2011)	N/A
Venlafaxine*	Effexor	capsule (extended release)*	37.5, 75, 150 mg*	MHRA by 3/2011	Antidepressant	Generalized anxiety disorder, Major depressive disorder, Panic disorder, Social phobia	Capsaicin, Celecoxib, Colchicine, Ibuprofen lysine, Tapentadol hydrochloride	N/A	Y	expected in US by Q2/2012

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