

	PRODUCT (INN NAME)	ATC CODE	THERAPEUTIC INDICATION(S)		DOSSIER STATUS	DOSSIER LEGAL BASIS
1.	MORPHINE HCl 5mg, 10mg, 20mg, 30mg IR tablets	N02AA01	Treatment of severe pain		Available - Registered in EU	Generic & WEU
2.	METHADONE HCl 5mg, 10mg, 20mg, 40mg tablets	N07BC02	Treatment of severe pain	Methadone substitution therapy (Treatment of opioid dependency)	Available - Registered in EU	Generic & WEU
3.	AMITRIPTYLINE HCl 10mg, 25mg, 50mg film-coated tablets	N06AA09	Depression	Chronic neuropathic pain	Available - Registered in EU	Generic & WEU
4.	AMITRIPTYLINE HCl 75mg film-coated tablets NEW	N06AA10	Depression	Chronic neuropathic pain	Available - before registration	Generic & WEU
5.	VALSARTAN 80mg, 160mg, 320mg film-coated tablets	C09CA03	Congestive Heart Failure, Myocardial Infarction	Treatment of hypertension	Available - with technological transfer	Generic
6.	DROTAVERINE HCl 40mg, 80mg tablets	A03A D02	Treatment of smooth muscle spasms of biliary and urinary origin; adjunct to other pharmacological treatment in smooth muscle spasms of gastrointestinal origin; tension type headache; dysmenorrhoea		Available - Registered in EU & in Asia	Generic
7.	DIOSMIN/ HESPERIDIN 450mg/ 50mg f.c. tablets - NEW	C05CA53	Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, restless leg at bedtime)	Treatment of functional symptoms related to acute hemorrhoidal attack.	Available - Registered in EU	WEU
8.	DIOSMIN/ HESPERIDIN 900mg/ 100mg f.c. tablets - NEW	C05CA53	Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, restless leg at bedtime)	Treatment of functional symptoms related to acute hemorrhoidal attack.	Available - under registration in EU	WEU
9.	ACETYLSALICYLIC ACID / CAFFEINE 500mg/ 50mg tablets	N02BA51	Relieving pain and reducing inflammation, high temperature and fever		Available - Registered in EU	Generic
10.	BENDROFLUMETHIAZIDE 2,5mg, 5mg tablets	C03AA01	Treatment of high blood pressure and fluid retention (oedema) associated with kidney, liver or heart problems and pre-menstrual syndrome		Available - before registration	Generic
11.	CODEINE PHOSPHATE HEMIHYDRATE 10mg, 15mg, 20mg, 30mg tablets	R05DA04	Codeine is indicated in patients older than 12 years of age for the treatment of acute moderate pain which is not considered to be relieved by other analgesics such as paracetamol or ibuprofen (alone)	Codeine is indicated in patients older than 12 years of age for the symptomatic relief of unproductive cough and diarrhoea	Available - Registered in EU	Generic
12.	DEXKETOPROFEN 25mg film-coated tablets - NEW	M01AE17	Symptomatic treatment of pain of mild to moderate intensity, such as musculo-skeletal pain, dysmenorrhoea, dental pain		Available - Registered in EU	Generic
13.	ACRIVASTINE / PSEUDOEPHEDRINE 8mg/ 60mg hard capsules - NEW	R06AX18	Treatment of allergic rhinitis		Available - Registered in EU	Generic
14.	DEXAMPHETAMINE SULFATE 5mg, 10mg, 20mg tablets - NEW	N06BA02	Treatment of attention deficit/hyperactivity disorder (ADHD) in children and adolescents aged 6-17 years, when response to another medicine, methylphenidate, is not sufficiently effective		Available - under registration in EU	WEU & Generic

