

ONCOLOGY ORALS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Axitinib	Tabs	1 mg, 3mg, 5mg & 7 mg	Renal Cancer		√	√	Available
Capecitabine	Tabs	150mg & 500mg	Breast Cancer	√	√	√	Available
Capecitabine	DT	150mg, 500mg and 1000 mg	Breast Cancer			√	Available
Cyclophosphamide	Caps	25 mg & 50mg	Lymphoma	√		√	Available
Erlotinib	Tabs	25 mg, 100 mg, 150 mg	Lung Cancer	√	√	√	Available
Ibrutinib	Caps	140mg	Leukaemia	√		√	Available
Imatinib mesylate	Tabs	100mg & 400mg	Leukaemia	√	√	√	Available
Lenvatinib	Caps	4mg & 10mg	Renal, HCC and Thyroid Cancer	√		√	Available
Nilotinib	Caps	50mg, 150mg & 200 mg	Leukaemia				Available
Sunitinib maleate	Caps	12.5mg, 25mg, 37.5mg & 50 mg	Renal, Gastrointestinal and Pancreatic		√	√	Available
Thalidomide	Caps	50mg	Multiple Myeloma		√	√	Available
Sunitinib	Oral susp.	10mg/ml	Renal, Gastrointestinal and Pancreatic				Available
Imatinib	Oral soln.	80mg/mL	Leukaemia			√	Available
Bicalutamide	Tabs	50mg	Metastatic Prostate Cancer				Available
Capecitabine	Oral susp.	200 mg/mL	Breast Cancer				Available
Lenalidomide	Oral susp.	5 mg/mL	Multiple Myeloma, MDS				Available
Methotrexate	Oral Sol.	2.5 mg/mL	Leukaemia				Available
Erlotinib	Oral susp.	20 mg/mL	Lung Cancer				Available
Dasatinib	Oral susp.	40 mg/mL	Leukaemia				Available

ONCOLOGY INJECTIONS							
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Azacitidine	Powder for susp. for Inj.	25mg/ml (100mg/vial)	Leukemia	√	√	√	Available
Bendamustine HCl	For Inj.	25mg/vial & 100mg/vial	Leukemia		√	√	Available
Bortezomib	For Inj.	3.5 mg / Vial	Multiple Myeloma	√	√	√	Available
Bortezomib	Inj. (RTU)	3.5mg/1.4 mL	Multiple Myeloma	√	√	√	Available
Busulfan	Inj.	60 mg/10 mL (6 mg/mL)	Conditioning treatment for CML Patients	√	√	√	Available
Cabazitaxel (Single Vial)	Inj.	60mg /6ml	Metastatic Prostate Cancer		√		Available
Clofarabine	Inj.	20mg/20mL	Leukemia	√	√	√	Available
Cyclophosphamide	For Inj.	500 mg, 1g & 2g vial	Lymphoma			√	Available
Decitabine	For Inj.	50mg/vial	Bone Marrow Cancer			√	Available
Docetaxel	Inj.	20mg/ml, 80mg/4ml & 160mg/8ml	Breast Cancer and Prostate Cancer	√	√	√	Available
Docetaxel	Inj.	10mg/ml, 80mg/8ml & 160mg/16ml	Breast Cancer and Prostate Cancer	√		√	Available
Gemcitabine	Inj. (RTU)	200mg/5.26mL / 1g/26.3mL / 2g/52.6L (38mg/ml)	Lungs, Pancreas and Breast Cancer	√	√		Available
Irinotecan Hydrochloride	Solution for Infusion	20 mg/mL (100 mg/5 mL)(2 ml, 5 ml, 15 ml & 25 ml)	Colorectal Cancer	√	√	√	Available
Melphalan	For Inj. (With diluent)	50mg/vial	Multiple Myeloma	√	√	√	Available

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Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Pemetrexed	For Inj.	100mg/vial & 500mg/vial	Lung Cancer		√	√	Available
Pemetrexed	RTU	10mg/mL (10ml/50ml/ 85ml/100ml)	Lung Cancer	√	√	√	Available
Docetaxel (non-alcohol formula)	Inj.	20 mg/mL (1, 4 and 8 mL)	Breast Cancer and Prostate Cancer	√			Available
Gemcitabine	Inj.	200mg & 1 gm	Lungs, Pancreas and Breast Cancer				Available
Oxaliplatin	Inj.	5 mg/ml (10 ml, 20 ml & 40 ml)	Colon Cancer	√			Available
Paclitaxel	Suspension Injectable	100mg	Breast, lung and pancreatic cancer				Available
Zoledronic Acid	Inj.	4mg/ 5ml		√		√	Available
Betahistine Dihydrochloride	ODF	8mg, 16mg & 24 mg	Antihistamine	NA	√	√	Available
Melatonin	ODF	3mg	Sleep disorder / Insomnia	√	NA	√	Available
Methyl cobalamin (Vitamin B12)	ODF	1500mcg	Nutraceutical/ Dietary supplement	√	√	√	Available
Ondansetron	ODF	4 mg & 8mg	Antiemetic	NA	√	√	Available
Paracetamol	ODF	60mg & 120mg	Antipyretic	NA	√	NA	Available
Prucalopride	ODF	1mg & 2 mg	Constipation and bowel cleaning	NA	UD	NA	NA
Sildenafil Citrate	ODF	25 mg & 50 mg	Erectile dysfunction	NA	UD	NA	NA
Tadalafil	ODF	5mg, 10mg, 20mg	Erectile dysfunction	NA		√	Available

ONCOLOGY INJECTIONS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Vitamin D3 (Cholecalciferol)	ODF	400 / 600 / 800 / 1000 / 2000 / 4000 / 7000 / 10000 / 20000 / 25000 / 50000 / 60000 IU (12 STRENGTHS)	Nutraceutical/ Dietary supplement	2000 IU	√	NA	Available
Co Enzyme Q 10	ODF	100mg	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Vitamin K2 +Vitamin D3	ODF	70mcg+1000 IU	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
ORAL DISINTEGRATING FILMS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Bacillus Coagullans	ODF	5 Bill CFU	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Zinc	ODF	11 mg & 20 mg	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Biotin	ODF	5000 IU	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Caffeine+L Theanine +Methylcobalamin	ODF	50mg+15mg+1000 mcg	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Iron	ODF	14 mg	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Rivaroxaban	ODF	2.5mg, 10mg,15mg & 20 mg	Thrombo Embolism / Pulmonary Embolism	NA	UD	NA	NA
Pregabalin	ODF	25 mg, 50mg, 75mg (3 STRENGTHS)	Neuropathic pain	NA	√	NA	Available

ORAL DISINTEGRATING FILMS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Dexmedetomidine	ODF (sublingual)	120mg & 180 mg	Agitation associated with schizophrenia or bipolar I or II disorder	NA	UD	NA	NA
Bilastine	ODF	10mg & 20 mg	Antihistamine	NA	UD	NA	NA
Bilastine + Montelukast	ODF	20mg + 10 mg & 20mg + 20 mg	Antihistamine	NA	UD	NA	NA
Clobazam	ODF	5 mg, 10 mg & 20 mg	Epilepsy	NA	UD	NA	NA
Multivitamin	ODF	Vit. A 5000 IU + Vit. B 5 10 mg + Vit. B6 2 mg + Vit. B 7 300 mcg + Vit. B9 1000 mcg + Vit. C 30 mg + Vit. B 12 1000 mcg+ Vit. D3 400 IU + Vit. K 2 80 mcg + Iodine 150 mcg	Nutraceutical/ Dietary supplement	NA	UD	NA	NA
Simethicone	ODF	62.5 mg	Antiflatulent	√	NA	NA	Available
Green Tea Film 120 mg (AT STPL SITE)	Dissolvable Film	120mg	Nutraceutical/ Antioxidant	√	NA	NA	Available
TRANSDERMAL PATCHES							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Rotigotine	TDP	1, 2,3,4,6,8 & 20mg per 24 hrs	Parkinson's disease	UD	UD	NA	Available
Diclofenac Diethylamine	TDP	100 and 200 mg	Antiinflammatory	NA	NA	√	UD
Rivastigmine	TDP	4.6,9.5,13.3 mg/ 24hrs	Dementia/Alzheimer's disease	NA	NA	UD	NA
Scopolamine	TDP	1 mg / 72 hrs	Antiemetic		NA	NA	UD
Lidocaine	TDP	0.04	Local anaesthetic / Analgesic	UD	NA	NA	UD

TRANSDERMAL PATCHES							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Tetracaine	TDP	NA	Local anaesthetic / Analgesic	UD	NA	NA	UD
Methylsalicylate+ Menthol	TDP	10%+3%	Analgesic	UD	NA	NA	UD
NON ONCOLOGY - ORAL FORMULATIONS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Pirfenidone	Tab	267 mg & 801 mg	Autoimmune Disease/ Idiopathic Pulmonary Fibrosis	√	√	√	Available
Prucalopride	Tab	1mg & 2 mg	Alimentary Tract/Constipation and Bowel Cleansing		√	√	Available
Teriflunomide	Tab	7 mg & 14mg	Autoimmune Disease/Multiple Sclerosis	√	√	√	Available
Varenicline	Tab	0.5 mg and 1 mg	Smoking Cessation	√	√	√	Available
Dimethylfumerate	DR Caps	120 mg & 240 mg	Autoimmune Disease/Multiple Sclerosis	√		√	Available
Tenofovir Alafenamide	Tab	25 mg	Hepatitis B Viral Infection			√	Available
Macitentan	Tab	10 mg	Cardiovascular/Pulmonary Arterial Hypertension				Available
Selexipag	Tab	0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.8 mg	Cardiovascular/Hypertension				Available
Tranexamic acid	Tab	650 mg	Hemostatis/Prevent excessive bleeding				Available
Tranexamic acid	Tab	250 and 500 mg	Hemostatis/Prevent excessive bleeding				Available

NON ONCOLOGY - INJECTABLES							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Vasopressin	Inj.	0.2, 0.4 and 0.6 IU/mL	Cardiovascular/Blood Pressure increase				Available
Desmopressin Acetate (Room Temp Stable Injection)	Inj.	0.004 mg/mL	Diabetis/Central diabetes insipidus				Available
TOPICAL FORMULATIONS							
Product Name	Dosage Form	Strengths	Indication	US Filling status	EU Filling status	ROW Filling status	CTD Availability
Tranexamic acid	Spray	10% w/v (50 mL & 100 mL)	Wound Management/Wound Healing			√	Available
Intimate Cleansing	Spray	100 ml (1mg/mL)	Intimate Wash Solution				Available
Acyclovir	Cream	0.05	Antiviral/Cold Sores				Available