

Manufacturing and Marketing permission issued from SND Division from
29.03.2019 to 29.04.2019.

S. No	Drug Name	Composition	Indication	Date of Approval
1	Donepezil Hydrochloride Orally Disintegrating Strips (Additional dosage form)	Each Orally Disintegrating Strips Contains: Donepezil Hydrochloride 5/10 mg	For the treatment of mild to moderate severe Alzheimer's Dementia. With the condition:- To be sold by retail on the prescription of Neurologists only.	11.01.2019
2	Tapentadol Hydrochloride capsule 50mg (New dosage form)	Each capsule contains: Tapentadol Hydrochloride 50mg	For relief of moderate to severe acute pain in adults 18 years of age or older.	30.01.2019
3	Midodrine Hydrochloride tablet 2.5mg, 5mg and 10mg (Additional strength)	Each tablet contains: Midodrine Hydrochloride 2.5mg, 5mg and 10mg	It is indicated in the treatment of symptomatic orthostatic hypotension. With the condition:- To be sold by retail on the prescription of Cardiologists only.	20.02.2019
4	Ribociclib film coated tablet 200mg (Additional indication)	Ribociclib succinate 254.40mg eq. To Ribociclib 200mg	Ribociclib in combination with an aromatase inhibitor for the treatment of pre/peri-menopausal or post-menopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2(HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. With the condition: To be sold by retail on the prescription of an Oncologist only.	13.03.2019
5	Azacitidine for injection 150mg/vial (Additional strength)	Each vial contains: Azacitidine. 150mg Lyophilized powder for injection (for subcutaneous or Intravenous use)	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome. With the condition: to be sold by retail on the prescription of an Oncologist only.	25.03.2019
6	Lenvatinib capsule 4mg/10mg (Additional Indication)	Each capsule contains: Lenvatinib mesylate 4.90mg eq. To Lenvatinib 4mg., Lenvatinib mesylate 12.25 mg eq. To	For the first line treatment of patients with unresectable hepatocellular carcinoma. With the condition: to be sold by retail on the prescription of an Oncologist only.	26.03.2019

		Lenvatinib 10mg.		
7	Primidone tablet 50mg (Additional Strength)	Each uncoated tablet contains: Primidone USP 50mg	It is indicated for the management of grand mal and psychomotor (temporal lobe) epilepsy. It is also of value in the management of focal or jacksonian seizures, myoclonic jerks and akinetic attacks. Management of essential tremor. With the condition: To be sold by retail on the prescription of a Neurologist only.	15.04.2019