

Drugs and Devices Division

Drug Submission Status

Report for December 2018

Complete Streamlined Multiple-Source

Submissions for Off-Formulary Interchangeability

The Ministry of Health and Long-Term Care has received complete submissions for the following streamlined multiple-source drug products for Off-Formulary Interchangeability (OFI) designation. Subject to confirmation of Drug Identification Numbers (DIN) and prices by the manufacturers, as well as review and approval by the Executive Officer, these products may be designated as OFI drugs in a future Formulary update. Final OFI designation status will be communicated when the Formulary update is published on the Ministry website and via a DDD Notice.

Manufacturer	Product	Reference Product	Generic Name	Strength	Dosage Form	DIN
Apotex Inc.	Apo-Vardenafil	Levitra	vardenafil hydrochloride	5mg	tablet	02471647
Apotex Inc.	Apo-Vardenafil	Levitra	vardenafil hydrochloride	10mg	tablet	02471655
Apotex Inc.	Apo-Vardenafil	Levitra	vardenafil hydrochloride	20mg	tablet	02471663
Apotex Inc.	Apo-Ambrisentan	Volibris	ambrisentan	5mg	tablet	02475375
Apotex Inc.	Apo-Ambrisentan	Volibris	ambrisentan	10mg	tablet	02475383
Marcan Pharmaceuticals Inc.	Mar-Cinacalcet	Sensipar	cinacalcet	30mg	tablet	02480298

Manufacturer	Product	Reference Product	Generic Name	Strength	Dosage Form	DIN
Marcan Pharmaceuticals Inc.	Mar-Cinacalcet	Sensipar	cinacalcet	60mg	tablet	02480301
Marcan Pharmaceuticals Inc.	Mar-Cinacalcet	Sensipar	cinacalcet	90mg	tablet	02480328
Natco Pharma (Canada) Inc.	Nat-Bosentan	Tracleer	bosentan monohydrate	62.5mg	FC tablet	02467984
Natco Pharma (Canada) Inc.	Nat-Bosentan	Tracleer	bosentan monohydrate	125mg	FC tablet	02467992