

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Drug Submission Status

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 an OPDP Notice.

Manufacturer	Product	Reference Product	Generic Name	Strength	Dosage Form	DIN
Apotex Inc.	Apo-Montelukast	Singulair	montelukast sodium	10mg	FC tablet	02374609
Cobalt Pharmaceuticals Company	Co Betahistine	Serc	betahistine hydrochloride	16mg	tablet	02374757
Cobalt Pharmaceuticals Company	Co Betahistine	Serc	betahistine hydrochloride	24mg	tablet	02374765
Mylan Pharmaceuticals ULC.	Mylan-Montelukast	Singulair	montelukast sodium	10mg	FC tablet	02368226
Pharmascience Inc.	Pms-Montelukast FC	Singulair	montelukast sodium	10mg	FC tablet	02373947
Pharmascience Inc.	Pms-Montelukast	Singulair	montelukast sodium	5mg	chewable tablet	02354985

Sandoz Canada Inc.	Sandoz Montelukast	Singulair	montelukast sodium	10mg	FC tablet	02328593
Sandoz Canada Inc.	Sandoz Montelukast	Singulair	montelukast sodium	5mg	chewable tablet	02330393
Sandoz Canada Inc.	Sandoz Montelukast	Singulair	montelukast sodium	4mg	granules	02358611
Teva Canada Limited	Teva-Montelukast	Singulair	montelukast sodium	10mg	FC tablet	02355523
Teva Canada Limited	Teva-Montelukast	Singulair	montelukast sodium	5mg	chewable tablet	02355515

Updated: November 18, 2011