

Ministry of Health

Health Programs and Delivery Division

Drug Submission Status

Report for November 2023

Complete Streamlined Multiple-Source Submissions for Future Formulary Listing

The Ministry of Health has received complete submissions for the following streamlined multiple-source drug products for listing on the Ontario Drug Benefit Formulary. 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 listed as benefits in a future Formulary update. Final listing status will be communicated when the Formulary update is published on the Ministry website and via an HPDD Notice.

| Manufacturer | Product | Reference Product | Generic Name | Strength | Dosage Form | DIN |
|--------------------|------------------------|-------------------|---|---------------|-------------|----------|
| Nora Pharma | NRA-Candesartan HCTZ | Atacand Plus | CANDESARTAN CILEXETIL & HYDROCHLOROTHIAZIDE | 16 mg/12.5 mg | tablet | 02531240 |
| Nora Pharma | NRA-Candesartan HCTZ | Atacand Plus | CANDESARTAN CILEXETIL & HYDROCHLOROTHIAZIDE | 32 mg/12.5 mg | tablet | 02531259 |
| Nora Pharma | NRA-Candesartan HCTZ | Atacand Plus | CANDESARTAN CILEXETIL & HYDROCHLOROTHIAZIDE | 32 mg/25 mg | tablet | 02531267 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 10 mg | ER capsule | 02536943 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 15 mg | ER capsule | 02536951 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 20 mg | ER capsule | 02536978 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 30 mg | ER capsule | 02536986 |

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| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 40 mg | ER capsule | 02536994 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 50 mg | ER capsule | 02537001 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 60 mg | ER capsule | 02537028 |
| Pharmascience Inc. | Pms-Methylphenidate CR | Biphentin | METHYLPHENIDATE HYDROCHLORIDE | 80 mg | ER capsule | 02537036 |
| Mantra Pharma Inc. | M-Citalopram | Celexa | CITALOPRAM HYDROBROMIDE | 20 mg | tablet | 02467836 |
| Mantra Pharma Inc. | M-Citalopram | Celexa | CITALOPRAM HYDROBROMIDE | 40 mg | tablet | 02467844 |
| Mantra Pharma Inc. | M-Dorzolamide-Timolol | Cosopt | DORZOLAMIDE HCL & TIMOLOL MALEATE | 20 mg/mL & 5 mg/mL | ophthalmic solution | 02537796 |
| Sivem Pharmaceuticals | Fluconazole | Diflucan | FLUCONAZOLE | 50 mg | tablet | 02534886 |
| Sivem Pharmaceuticals | Fluconazole | Diflucan | FLUCONAZOLE | 100 mg | tablet | 02534894 |
| Sanis Health Inc. | Flecainide | Tambocor | FLECAINIDE ACETATE | 50 mg | tablet | 02534800 |
| Sanis Health Inc. | Flecainide | Tambocor | FLECAINIDE ACETATE | 100 mg | tablet | 02534819 |
| Pharmaris Canada Inc. | PRZ-Doxycycline | Vibra-Tabs | DOXYCYCLINE HYCLATE | 100 mg | tablet | 02536250 |
| Teva Canada Limited | Teva-Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02507196 |
| Teva Canada Limited | Teva-Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02507218 |
| Teva Canada Limited | Teva-Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02507226 |
| Taro Pharmaceuticals Inc. | Taro-Rivaroxaban | Xarelto | RIVAROXABAN | 2.5 mg | tablet | 02526786 |

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| Taro Pharmaceuticals Inc. | Taro-Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02483807 |
| Taro Pharmaceuticals Inc. | Taro-Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02483815 |
| Taro Pharmaceuticals Inc. | Taro-Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02483823 |
| Apotex Inc. | Apo-Rivaroxaban | Xarelto | RIVAROXABAN | 2.5 mg | tablet | 02541734 |
| Apotex Inc. | Apo-Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02470497 |
| Apotex Inc. | Apo-Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02470500 |
| Apotex Inc. | Apo-Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02470519 |
| Pharmascience Inc. | Pms-Rivaroxaban | Xarelto | RIVAROXABAN | 2.5 mg | tablet | 02527537 |
| Pharmascience Inc. | Pms-Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02512041 |
| Pharmascience Inc. | Pms-Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02512068 |
| Pharmascience Inc. | Pms-Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02512076 |
| Sandoz Canada Inc. | Sandoz Rivaroxaban | Xarelto | RIVAROXABAN | 2.5 mg | tablet | 02537877 |
| Sandoz Canada Inc. | Sandoz Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02482223 |
| Sandoz Canada Inc. | Sandoz Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02482231 |
| Sandoz Canada Inc. | Sandoz Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02482258 |
| Dr. Reddy's Laboratories Canada Inc. | Reddy-Rivaroxaban | Xarelto | RIVAROXABAN | 2.5 mg | tablet | 02524503 |

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| Dr. Reddy's Laboratories Canada Inc. | Reddy- Rivaroxaban | Xarelto | RIVAROXABAN | 10 mg | tablet | 02472414 |
| Dr. Reddy's Laboratories Canada Inc. | Reddy- Rivaroxaban | Xarelto | RIVAROXABAN | 15 mg | tablet | 02472430 |
| Dr. Reddy's Laboratories Canada Inc. | Reddy- Rivaroxaban | Xarelto | RIVAROXABAN | 20 mg | tablet | 02472422 |
| Apotex Inc. | Apo- Dapagliflozin- Metformin | Xigduo | DAPAGLIFLOZIN & METFORMIN | 5 mg/ 850 mg | tablet | 02536153 |
| Apotex Inc. | Apo- Dapagliflozin- Metformin | Xigduo | DAPAGLIFLOZIN & METFORMIN | 5 mg/ 1000 mg | tablet | 02536161 |