Government of Canada Gouvernement du Canada

Canada

Recalls and safety alerts

OraVerse Injection (2018-04-20)

Report a Concern

Starting date:	April 20, 2018
Posting date:	April 27, 2018
Type of communication:	Drug Recall
Subcategory:	Drugs
Hazard classification:	Type III
Source of recall:	Health Canada
Issue:	Product Safety
Audience:	General Public, Healthcare Professionals, Hospitals
Identification number:	RA-66664

- Reason
- Depth of distribution
- Affected products

Affected Products

OraVerse Injection

Reason

Out of specification for phentolamine mesylate assay in lot D01894D. Out of trend for degradation product impurity (phentolamide) in lots D01894D and D01894F.

Depth of distribution

Wholesalers in ON, QC, AB and BC

Affected products

OraVerse Injection

DIN, NPN, DIN-HM

DIN 02421666

Dosage form

Powder for solution

Strength

phentolamine mesylate Injection 0.4 mg/1.7 mL

Lot or serial number

- D01894D
- D01894F

Companies

Recalling Firm	N/A
Marketing Authorization Holder	SEPTODONT 58 Rue Du Pont De Creteil, St-Maur-Des-Fosses, Val-De-Marne, France

Date modified: 2018-04-27