Fibristal 5MG (2020-09-24)

Report a Concern (http://www.healthycanadians.gc.ca/report-signalez/index-eng.php)

Starting date:	September 24, 2020
Type of communication:	Drug Recall
Subcategory:	Drugs
Hazard classification:	Type II
Source of recall:	Health Canada
Issue:	Product Safety
Audience:	General Public, Healthcare Professionals, Hospitals
Identification number:	RA-74051

Last updated: 2020-09-28

Summary

- **Product:** Fibristal 5MG

Reason

During post-market experience, rare cases of liver injury, including cases of serious liver impairment requiring liver transplantation, were reported in patients using ulipristal acetate 5mg.

Depth of distribution

Wholesalers, Healthcare establishments, Physicians

Affected products

Fibristal 5MG

DIN, NPN, DIN-HIM

DIN 02408163

Dosage form

Tablet

Strength

Ulipristal Acetate 5MG

Lot or serial number

T7B236A
T7B231B
T85328B
T85329A
T02566A
T7B231A
T97577T

Companies

Recalling Firm	Allergan Inc. 500 Enterprise Blvd. Suite 500 Markham L65 0B5

Ontario
CANADA

Marketing Authorization Holder Allergan Inc.
500 Enterprise Blvd. Suite 500
Markham
L65 0B5
Ontario
CANADA

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