LEDERLE LEUCOVORIN- calcium folinate tablet
FARMASIERRA MANUFACTURING SL

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Lederle Leucovorin_"Unapproved drug for use in drug shortage"

Letter

URGENT: Important Prescribing Information Letter

Subject: Temporary Importation of Lederle Leucovorin®(Calcium Folinate tablets, USP) from Canada to Address U.S. Drug Shortage

December 2025

Dear Health Care Provider,

Due to the sho1tage of Leucovorin Calcium tablets, USP in the United States (U.S.) market, Pfizer is coordinating at the request of the U.S. Food and Drng Administration (FDA) to temporarily import unapproved Lederle Leucovorin®(Calcium Folinate tablets, USP) 5 mg tablets marketed in Canada.

This product is manufactured by Pfizer's Contract Manufacturer, FannasielTa, located in Madrid, Spain. The FDA has not approved Pfizer's Lederle Leucovorin (Calcium Folinate tablets USP), 5 mg tablets in the U.S.; however, the FDA is pennitting the tempora1y impo1tation and distribution of this product. Leucovorin Calcium tablets, USP, is refelTed to as Calcium Folinate tablets, USP, outside of the U.S.

Effective immediately, and during this temporaiy period, Pfizer will distribute the following presentation(s) of unapproved Lederle Leucovorin®(Calcium Folinate, USP):

Product: Lederle Leucovorin®, Calcium Folinate USP
Strength: 5 mg Tablet
Packaging: 1 × 24 Bottle
NDC: 0069-5886-24
Batch: X773
Expiration Date: 04-30-2026
Canada Marketing Authorization: DIN 02170493 / GTIN 066063817221
Product: Lederle Leucovorin®, Calcium Folinate USP
Strength: 5 mg Tablet
Packaging: 1 × 24 Bottle
NDC: 0069-5886-24
Batch: X830
Expiration Date: 10-31-2026
Canada Marketing Authorization: DIN 02170493 / GTIN 066063817221
Product: Lederle Leucovorin®, Calcium Folinate USP
Strength: 5 mg Tablet
Packaging: 1 × 24 Bottle
NDC: 0069-5886-24

Batch: Z361
Expiration Date: 03-31-2027
Canada Marketing Authorization: DIN 02170493 / GTIN 066063817221
Product: Lederle Leucovorin®, Calcium Folinate USP
Strength: 5 mg Tablet
Packaging: 1 × 100 Bottle
NDC: 0069-5886-99
Batch: X831
Expiration Date: 10-31-2026
Canada Marketing Authorization: DIN 02170493 / GTIN 066063817207
Product: Lederle Leucovorin®, Calcium Folinate USP
Strength: 5 mg Tablet
Packaging: 1 × 100 Bottle
NDC: 0069-5886-99
Batch: Z362
Expiration Date: 03-31-2027
Canada Marketing Authorization: DIN 02170493 / GTIN 066063817207

It is important to note that there are differences between the FDA-approved Leucovorin Calcium, USP products and the Calcium Folinate tablets, USP, marketed in Canada by Pfizer, Inc. Please see the product side-by-side label comparison table, where FDA-approved Leucovorin Calcium Tablets, USP 5 mg, manufactured by Teva Pharmaceuticals USA, Inc., is used as a reference.

It is important to note the following differences:

Lederle Leucovorin® (Calcium Folinate tablets, USP) 5 mg tablets is indicated for diminishing the toxicity and counteracting the effect of impaired methotrexate elimination. Treatment of megaloblastic anemias due to folate deficiency, as in sprue, nutritional deficiency, megaloblastic anemias of pregnancy and infancy. FDA-approved Leucovorin Calcium, USP, product is contraindicated for pernicious anemia and other megaloblastic anemias caused by vitamin B12 deficiency.
The container label will display the text used and approved for marketing Lederle Leucovorin® (Calcium Folinate tablets, USP) in Canada containing English and French text.
Health Canada has not authorized an indication for pediatric use for the imported product. FDA-approved Leucovorin Calcium, USP, includes a specific warning in the Drug Interactions section regarding folic acid which in large amounts may counteract the antiepileptic effect of phenobarbital, phenytoin and primidone, and increase the frequency of seizures in susceptible children. The Canadian Product Monograph does not mention this specific age group (10-12).
The Canadian Product Monograph includes a Post Marketing section addressing Adverse Drug Reactions, including that cases of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), some fatal, have been reported in patients receiving calcium folinate in combination with other agents known to be associated with these disorders. A contributory role of leucovorin in these occurrences of SJS/TEN cannot be excluded. Fatalities have occurred as a result of gastrointestinal toxicity (predominantly mucositis and diarrhea) and myelosuppression. In patients with diarrhea, rapid clinical deterioration leading to death can occur.
The barcode of the imported product label may not register accurately on the U.S. scanning systems. Institutions should manually input the important product information

into their systems and confirm that the barcode, if scanned, provides correct information. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.
The packaging of the imported product does not include serialization information. Pfizer’s Calcium Folinate, USP, marketed in Canada, does not meet the Drug Supply Chain Security (DSCSA) standards for Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs. FDA has created an exemption for the product due to the shortage.
Leucovorin Calcium tablet, USP is available only by prescription in the U.S. However, the imported product does not have the statement “Rx only” on the labeling.

Please refer to the package inse1i for the FDA approved Leucovorin Calcium, USP, full Prescribing fufonnation.

Adverse Events and Product Quality Complaints

To repo1i adverse reactions or quality issues, contact Pfizer at 1-800-438-1985.

Adverse reactions or quality problems experienced with the use of this product may be repo1ied to the FDA's MedWatch Adverse Event Repo1iing Program either online, by regular mail, or by fax:

Complete and submit the repo1i Online: www.fda.gov/medwatch/repo1t.htm
Regular mail or Fax: download f01m www.fda.gov/MedWatch/getfonns.htm or call 1-800-332-1088 to request a repo1iing fonn, then complete and return to the address on the pre-addressed f01m, or submit by fax to 1-800-FDA-0l 78 (1-800-332-0178)
When repo1iing, please indicate product is Lederle Leucovorin from Pfizer Canada and provide the lot number

Contact Information

Please contact Pfizer Customer Service at 1-800-533-4535 or dropships@pfizer.com (Mon.-Fri. 8am-5:30pm ET) or your Pfizer representative for any questions you may have regarding this notification.

Sincerely,

Pfizer fuc.

Caleb Haii

US PAVE Business Unit Lead

Lederle Leucovorin 24 tablets

Lederle Leucovorin 24 tablets

Lederle Leucovorin 100 tablets

Lederle Leucovorin 100 tablets

LEDERLE LEUCOVORIN

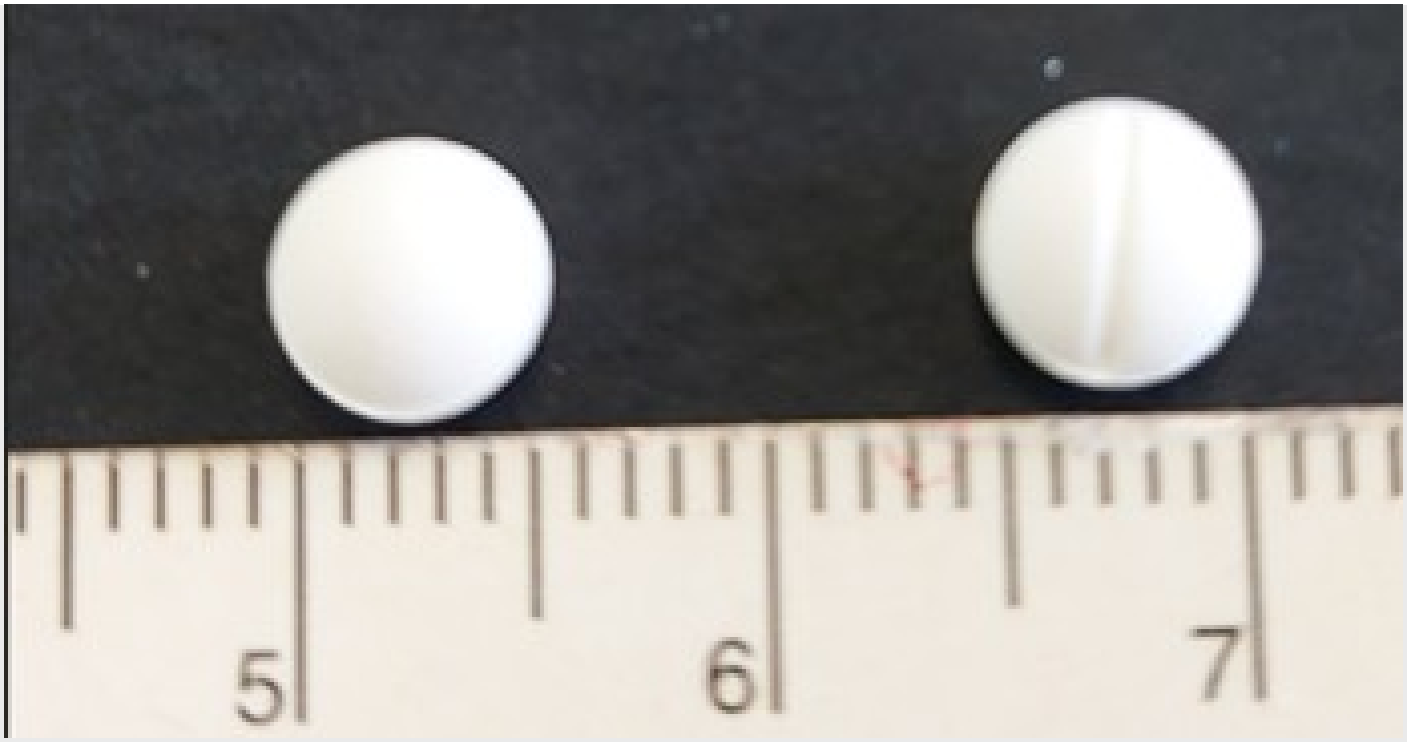
calcium folinate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73591-5886
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEUCOVORIN CALCIUM (UNII: RPR1R4C0P4) (LEUCOVORIN - UNII:Q573I9DVLP)	LEUCOVORIN	5 mg

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73591-5886-2	24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/26/2025	
2	NDC:73591-5886-1	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/26/2025	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		11/26/2025	

Labeler - FARMASIERRA MANUFACTURING SL (466799991)

Registrant - HOSPIRA WORLDWIDE, LLC (963711309)

Establishment

Name	Address	ID/FEI	Business Operations
FARMASIERRA MANUFACTURING SL		466799991	manufacture(73591-5886) , analysis(73591-5886) , label(73591-5886) , pack(73591-5886)

Revised: 11/2025 FARMASIERRA MANUFACTURING SL