

MARPLAN- isocarboxacid tablet
MediLink A/S

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.

Temporary Importation of Marplan (isocarboxacid) Tablets to Address Critical Drug Shortage
IMPORTANT PRESCRIBING INFORMATION

December 20, 2018

Subject: Temporary Importation of Marplan® (isocarboxacid) Tablets to Address Critical Drug Shortage

Dear Healthcare Professional,

In order to address the critical shortage of Marplan® (isocarboxazid) 10 mg Tablets in the United States (US) market, Validus Pharmaceuticals LLC is coordinating with the U.S. Food and Drug Administration (FDA) to make Marplan available to our patients. Validus has initiated temporary importation of another manufacturer's Marplan (isocarboxacid) into the U.S. market. This product is manufactured and marketed in Denmark by MediLink.

At this time, no other entity except Validus Pharmaceuticals LLC is authorized by the FDA to import and distribute MediLink's Marplan (isocarboxacid) 10 mg Tablets in the United States. FDA has not approved MediLink's Marplan (isocarboxacid) 10 mg Tablets but does not object to its importation into the United States. Effective immediately, and during this temporary period, Validus will offer the following product:

Product Name and Description	Bottle Count	NDC Code	Manufacturer
Marplan (isocarboxacid) 10 mg Tablets	56 tablets	72604-032-01	MediLink

It is important to note the following:

- The labeling is in Danish. MediLink's Marplan (isocarboxacid) 10 mg Tablets' labeling, with the exception of the product name "Marplan", will appear in Danish. There are key differences in the labeling between Validus' Marplan and MediLink's Marplan. A side by side comparison of the FDA approved Marplan (isocarboxazid) Prescribing Information and the imported Marplan (isocarboxacid) product information is included at the end of this letter.
- The tablets have different appearance. MediLink's Marplan (isocarboxacid) 10 mg tablets are "dull pink" in color whereas Validus' Marplan (isocarboxazid) 10 mg tablets are "peach-colored." MediLink's Marplan 10 mg tablets are imprinted with "CL 3M3" whereas Validus' Marplan 10 mg tablets are imprinted with "Marplan" and "10" on one side. Please refer to the "Product Comparison" table at the end of this letter for details and images.
- The barcode may not register accurately in the U.S. scanning systems. Institutions should manually input the product into their systems and confirm that the barcode Marplan DHCP Letter Page 1 of 22 systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

To order, or if you have any questions about MediLink's Marplan, please contact Validus Customer Service by phone at 1-866-982-5438 or by e-mail at info@validuspharma.com.

To report Adverse Events or Quality Problems among patients who have received - MediLink's Marplan, please contact Validus at 1-866-982-5438 or by e-mail at info@validuspharma.com. Adverse events or quality problems may also be reported to FDA's MedWatch Adverse reporting Program

either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/Medwatch/getforms.htm or call 1- 800-332-1088 to request a reporting form. Complete and return the form to the address on the pre-addressed form, or submit it by fax to 1-800-FDA-0178 (1-800- 332-1078).

If you have any questions about the information contained in this letter or the safe and effective use of MediLink's Marplan (isocarboxacid) 10mg Tablets, please contact Validus at 1-866-982- 5438 or by e-mail at info@validuspharma.com.

Sincerely,

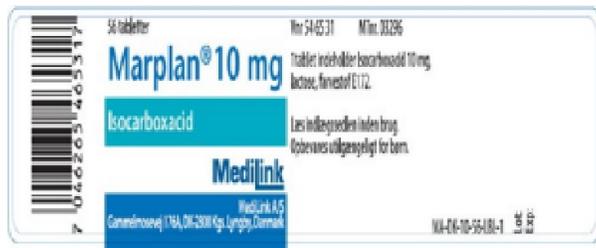
Gina Walljasper

Sr. Director Regulatory and Quality Operations

Validus Pharmaceuticals LLC

Principal Display Panel - Marplan (isocarboxacid) 10mg Tablets

Marplan 10 mg is a round and flat, pink tablet with a break line on one side and labeled CL 3M3 on the other side.



Marplan® 10 mg

Isocarboxacid

(British English Spelling)

MARPLAN

isocarboxacid tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:72604-032
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOCARBOXAZID (UNII: 34237V843T) (ISOCARBOXAZID - UNII:34237V843T)	ISOCARBOXAZID	10 mg

Product Characteristics

Color	pink (Dull Pink)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	CL;3M3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72604-032-01	1 in 1 CARTON	12/20/2018	
1		56 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		12/20/2018	

Labeler - MediLink A/S (587619958)

Revised: 12/2018

MediLink A/S