

DEFERAL- deferoxamine mesylate injection, powder, for solution
MITEM PHARMA

NDC 0078-0467-61

Desferal®

deferoxamine mesylate
for injection USP

500 mg per vial

For SC, IM or IV Use

Reconstituted Exp.:
See package insert.

Turbid solutions should not be used.
Store at 20°C to 25°C (68°F to 77°F),
excursions permitted between 15°C
and 30°C (59°F and 86°F).

Manufactured by:
Novartis Pharma Stein AG
Stein, Switzerland
and
Wasserburger Arzneimittelwerk
GmbH
83512 Wasserburg
Germany

Distributed by:
Novartis Pharmaceuticals
Corp.
East Hanover, NJ 07936

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Rx only

700712 US



EXP./LOT

Laufrichtung
 Machine direction

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DEFERAL
 deferoxamine mesylate injection, powder, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:87081-467
Route of Administration	SUBCUTANEOUS, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEFEROXAMINE MESYLATE (UNII: V9TKO7EO6K) (DEFEROXAMINE - UNII:J06Y7MXW4D)	DEFEROXAMINE MESYLATE	500 mg in 5 mL

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87081-467-91	4 mL in 1 VIAL; Type 0: Not a Combination Product	04/02/1968	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016267	04/02/1968	

Labeler - MITEM PHARMA (500300624)

Establishment

Name	Address	ID/FEI	Business Operations
Excella GmbH & Co. KG Nürnberger Str. 12 90537 Feucht Germany		329809800	api manufacture(87081-467) , analysis(87081-467)

Establishment

Name	Address	ID/FEI	Business Operations
Novartis Pharma AG Lichtstrasse 35 CH-4056 Basel Switzerland		482347168	analysis(87081-467)

Establishment

Name	Address	ID/FEI	Business Operations
SGS International Services Laboratory (ISL) Limited Ringaskiddy Cork, P43 FR 63 Ireland (IRL)		985785798	analysis(87081-467)

Establishment

Name	Address	ID/FEI	Business Operations
SGS Institut Fresenius GmbH Tegeler Weg 33 10589 Berlin Germany		341259550	analysis(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
SGS Institut Fresenius GmbH Im Maisel 14 65232 Taunusstein Germany		317219699	analysis(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein Switzerland		488152505	manufacture(87081-467) , analysis(87081-467) , pack(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmanalytica SA Via Balestra 6600 Locarno Switzerland		487967499	analysis(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Packaging Coordinators, LLC 3001 Red Lion Road Philadelphia, PA 19114		078525133	pack(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Wasserburger Arzneimittelwerk GmbH Herderstraße 1,2 and Molkerei-Bauer-Straße 18 83512 Wasserburg Germany		326482247	manufacture(87081-467) , analysis(87081-467) , pack(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Labor LS SE & Co. KG Mangelsfeld 4, 5, 6, Bad Bocklet, Bavaria 97708 Germany		314929072	analysis(87081-467)

Establishment			
Name	Address	ID/FEI	Business Operations
Solvias AG Römerpark 2 4303 Kaiseraugst Switzerland		480739627	analysis(87081-467)