

MONSELS SOLUTION- ferric subsulfate paste

Gynex Corporation

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.

Active Ingredients:

Ferric Subsulfate...20-22% by weight

Other ingredients include thickeners, preservatives and purified water.

Restricted to use by or on the order of a licensed healthcare professional.

Single-Use only. Do not reuse, discard after one use.

Keep cap tightly sealed and away from light.

Store at room temperature (15-30°C).

PRINCIPAL DISPLAY PANEL

The image shows the principal display panel for GYNEX Monsel's Ferric Subsulfate Solution. At the top, it lists 'REF 5055', '8ml', and 'NDC'. The product name 'GYNEX Monsel's Ferric Subsulfate Solution' is prominently displayed in purple. To the left, there is a vertical text block containing 'Active Ingredients' information, usage restrictions, and contact information for GYNEX. At the bottom, there is a caution statement and a lot number 'LOT' next to a stylized 'D' logo.

REF 5055 8ml NDC

Active Ingredients
Ferric Subsulfate ... 20 – 22% by weight
Other ingredients include thickeners, preservatives, and purified water.

Restricted to use by or on the order of a licensed healthcare professional.
Single-Use only. Do not reuse, discard after one use. Keep cap tightly sealed and away from light. Store at room temperature (15 – 30°C). Made in the U.S.A. Distributed by:
GYNEX – 1 (888) 486-4644
Redmond, WA 98052

GYNEX®
Monsel's
Ferric Subsulfate Solution

5055 BottleLabel REV C 01.20.10 **CAUTION:** U.S. Federal Law restricts to use by or on the order of a licensed physician.

LOT

MONSELS SOLUTION			
ferric subsulfate paste			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48992-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FERRIC SUBSULFATE (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:91O4LML611)		FERRIC CATION	210 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC SULFATE (UNII: 3HWS7HF5XD)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48992-001-01	14 g in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product	03/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/13/2020	

Labeler - Gynex Corporation (012997685)

Establishment

Name	Address	ID/FEI	Business Operations
Diversified Chemical Products, Inc.		030317424	manufacture(48992-001)

Revised: 10/2021

Gynex Corporation