GYNEX MONSELS SOLUTION- ferric subsulfate paste
Premier Dental Products Company

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.

Gynex Monsels

Ferric Subsulfate 20-22% by weight

Other Ingredients include thickeners, preservatives, and purified water

Store at room temperature (15-30degC)

Keep cap tightly sealed

Protect from light

Mfg. for and distrib. by:

Gynex

North Richland Hills, TX

Do not reuse, discard after one use.

NDC 48783-113-08

Gynex Monsel's Ferric Subsulfate Paste

REF 5055

Monsel's Ferric Subsulfate Paste 20-22%, Non-Sterile, Single-Patient Use

12 single applications - 8mL vials, 12 rayon-tipped applicators

GYNEX MONSELS SOLUTION ferric subsulfate paste			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:48783-113

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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FERRIC SULFATE (UNII: 3HWS7HF5XD)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48783-113-08	14 g in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product	11/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/29/2024	

Labeler - Premier Dental Products Company (014789663)

Establishment

Name	Address	ID/FEI	Business Operations
Diversified Chemical Products Inc		030317424	manufacture(48783-113)

Revised: 2/2025 Premier Dental Products Company