# **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.

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#### **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.

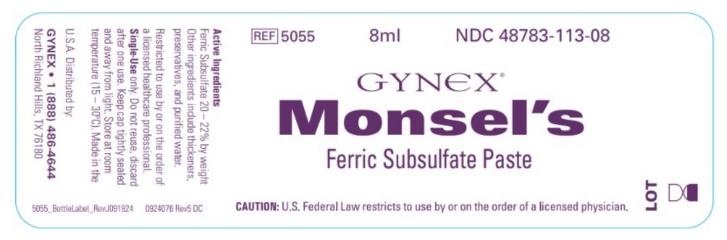
NDC 48783-113-08

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



# ferric subsulfate paste Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:48783-113

#### **Active Ingredient/Active Moiety**

#### **Ingredient Name**

**Basis of Strength Strength** 

FERRIC SUBSULFATE (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:9104LML611) 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
<b>1</b> NDC:48783- 113-08	14 g in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product	11/29/2024	

### **Marketing Information**

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	<b>Business Operations</b>
Diversified Chemical Products Inc		030317424	manufacture(48783-113)

Revised: 2/2025