

STIPTIK- ferric subsulfate solution
Island Kinetics, Inc. d.b.a. CoValence Laboratories

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.

HIGHLIGHTS OF PRESCRIBING INFORMATION
OTC #301; Stiptik Swab (100)

These highlights do not include all the information needed to use see full prescribing information for Initial U.S. Approval.

-----**DOSAGE AND ADMINISTRATION**-----

Active Ingredients: Ferric Subsulfate (Monsel's Solution) 0.20 - 0.22 gm Fe (1)

Purpose: Hemostatic Agent (1)

Uses: (1)

- Used as a styptic. Single use dose. Do not reuse.
- Stops local bleeding cause by minor surface cuts and abrasions.
- This prouct is intended for topical use only.

Warnings: For external use only. Avoid contact with the eyes. Stop use and ask a doctor if rash occurs. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. (1)

Directions: Break swabpoule and apply directly to minor cuts and abraisons as needed. (1)

Ingredients: Aqua (Water), Ferric Subsulfate (1)

Other information: Crystallization may occur if the product is exposed to temperatures below 22° C (70° F). Warming will re-dissolve the crystals. (1)

NDC: 66915-301-04 (1)

Revised: 1/2018

FULL PRESCRIBING INFORMATION: CONTENTS*
DOSAGE & ADMINISTRATION SECTION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

DOSAGE & ADMINISTRATION SECTION

Principal Display Panel



Stiptik Swabpoule

0.7 mL each swab
(100/carton)

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0.20 -0.22 gm Fe

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NDC: 66915-301-04

Distributed by CoValence® Laboratories
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Questions or comments (480) 897-0551 • covalence.com

STIPTIK

ferric subsulfate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66915-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERRIC SUBSULFATE (UNII: 3QJ8WS6V8H) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66915-301-04	100 in 1 CARTON	01/25/2018	12/31/2022
1	NDC:66915-301-03	1 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/25/2018	

Labeler - Island Kinetics, Inc. d.b.a. CoValence Laboratories (959735002)

Establishment

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. CoValence Laboratories		959735002	manufacture(66915-301)

Revised: 1/2022

Island Kinetics, Inc. d.b.a. CoValence Laboratories