

Indexing - product concept

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Food and Drug Administration

Reference Label Set Id: ff4941b3-9901-4aab-adcf-c5327bede34e

Application Product Concept

kit

Product Information

Product Type	INDEXING - PRODUCT CONCEPT	Item Code (Source)	3bb2a06a-64e7-1380-e8d7-189718b04a63
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		10 mL
Part 2		50 mL

Part 1 of 2

injection

Product Information

Item Code (Source)	be4be4ef-3629-2cac-c011-02ea955a7950
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM NITRITE (UNII: M0KG633D4F) (NITRITE ION - UNII:J39976L608)	SODIUM NITRITE	30 mg in 1 mL

Part 2 of 2

injection

Product Information

Item Code (Source)	06879002-6dea-3c2f-71c1-614568bd0e06
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM THIOSULFATE (UNII: HX1032V43M) (THIOSULFATE ION - UNII:LLT6XV39PY)	SODIUM THIOSULFATE	250 mg in 1 mL

Application Product Concept

Product Information

Product Type	INDEXING - PRODUCT CONCEPT	Item Code (Source)	d106808e-3051-96a1-aaa3-e4504dd8b3d6
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Marketing Information

Marketing Category	Application Number or Monograph Citation
NDA	NDA20 1444

Labeler - Food and Drug Administration (927645523)

Revised: 12/2017

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