

PHYTONADIONE- phytonadione injection, emulsion
Square Pharmaceuticals Ltd.

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.

Rx only

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 10mg/mL

Phytonadione
Injectable Emulsion, USP 10 mg/mL
Batch No. :
Mfg. Date :
EXHIBIT BATCH NOT FOR SALE

2000012346

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 1mg/0.5 mL

Phytonadione
Injectable Emulsion, USP 1mg/0.5 mL
Batch No. :
Mfg. Date :
EXHIBIT BATCH NOT FOR SALE

2000012347

PHYTONADIONE

phytonadione injection, emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76483-051
Route of Administration	PARENTERAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76483-051-31	1 mL in 1 AMPULE; Type 0: Not a Combination Product	04/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/10/2018	

PHYTONADIONE

phytonadione injection, emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76483-052
Route of Administration	PARENTERAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	1 mg in 0.5 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76483-052-30	0.5 mL in 1 AMPULE; Type 0: Not a Combination Product	04/10/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved drug other		04/10/2018	
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Labeler - Square Pharmaceuticals Ltd. (731487153)

Establishment

Name	Address	ID/FEI	Business Operations
Square Pharmaceuticals Ltd.		731487153	analysis(76483-051, 76483-052) , label(76483-051, 76483-052) , manufacture(76483-051, 76483-052) , pack(76483-051, 76483-052)

Revised: 4/2016

Square Pharmaceuticals Ltd.