

ADDEX-1000- naltrexone pellet, implantable
Advanced Pharmaceutical Technology, Inc.

Addex-1000

Naltrexone- in sterile dispenser.

Contains slow release Naltrexone 1 gram pellet. Each trocar contains 1 pellet of 1 gram Naltrexone base. This product is not validated to replace oral Naltrexone. Recommended dose of 1 pellet of 1 gram.

Caution:

Not to be used in conjunction with oral Naltrexone. Must be given only by a trained physician. This product is for single use only and the trocar discarded. Federal Law prohibits dispensing without a prescription.

Do Not Use-

if pouch is damaged or open since it will no longer be sterile.

STORE IN A COOL DRY PLACE. (TEMPERATURE NOT TO EXCEED 30 °C)

Each pellet contains: 1 Gram Naltrexone.

Plus Inactives: ethyl cellulose USP, polyvinyl pyrrolidone USP, stearic acid USP.

Package Labeling:



NDC 57377-010-00

ADDEX-1000[®]
1 GRAM - NALTREXONE

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LOT NUMBER: P-18-1

MANUFACTURED DATE: November, 2018

EXPIRATION DATE: November, 2020

FOR EXPORT ONLY

Manufactured by:
Advanced Pharmaceutical Technology
132 South Central Avenue | Elmsford, NY 10523

ADDEX-1000

naltrexone pellet, implantable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57377-010
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NALTREXONE (UNII: 5S6W795CQM) (NALTREXONE - UNII:5S6W795CQM)	NALTREXONE	1000 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57377-010-00	1 in 1 AMPULE; Type 0: Not a Combination Product	05/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/16/2018	

Labeler - Advanced Pharmaceutical Technology, Inc. (023237884)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Pharmaceutical Technology, Inc.		023237884	manufacture(57377-010) , pack(57377-010)

Revised: 10/2022

Advanced Pharmaceutical Technology, Inc.