

MKO MELT DOSE PACK- midazolam - ketamine hcl - ondansetron troche
Imprimis NJOF, LLC

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.

Storage and Handling

Store at 20° to 25° C (68° to 77° F)

Package Label



MKO TROCHE
Midazolam/Ketamine HCL/Ondansetron
3mg/25mg/2mg

Rev. 0

NDC: 71384-410-03

imprimis **Rx**

Active ingredients (per troche):

Midazolam 3mg, Ketamine HCL 25mg, Ondansetron 2mg

Inactive ingredients (per troche):

Stevia powder 4mg, Marshmallow flavor 0.005 mL,

Vanilla flavor 0.005 mL, Lemon flavor 0.005 mL,

Troche base 130mg

Lot: XXXXXXXX Date compounded: XXXXXXXX

Expires on: XXXXXXXX Store at 20 to 25°C

IMPRIMIS NJOF, LLC

1705 Route 46 West, Unit 6B Ledgewood, NJ 07852

(844) 446-6979

In case of adverse event contact:

www.fda.gov/medwatch or (800) FDA-1088

This is a compounded drug. NOT FOR RESALE. OFFICE USE ONLY.

MKO MELT DOSE PACK

midazolam - ketamine hcl - ondansetron troche

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71384-410
Route of Administration	SUBLINGUAL	DEA Schedule	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MIDAZOLAM (UNII: R60L0SM5BC) (MIDAZOLAM - UNII:R60L0SM5BC)	MIDAZOLAM	3 mg
KETAMINE HYDROCHLORIDE (UNII: O18YUO0I83) (KETAMINE - UNII:690G0D6V8H)	KETAMINE	25 mg
ONDANSETRON HYDROCHLORIDE ANHYDROUS (UNII: 2999F27MAD) (ONDANSETRON - UNII:4AF302ESOS)	ONDANSETRON	2 mg

Product Characteristics

Color	white (Off White)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71384-410-03	3 in 1 DOSE PACK; Type 0: Not a Combination Product	03/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/04/2019	

Labeler - Imprimis NJOF, LLC (080431967)

Registrant - Imprimis NJOF, LLC (080431967)