TRANSDERM-IQ- transderm-iq ointment
Direct_Rx

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TRANSDERM-IQ

For external use only

use only as directed. Read and follow all directions and warnings on this carton.
avoid contact with eyes and mucous membranes
do not use at the same time as other topical analgesics
do not use on open wounds, cuts, damaged or infected skin
do not use with bandage or heating pad.

Stop use and ask a doctor if

condition worsens
symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding or if you have sensitive skin, ask a health professional before use

Purified Water, Mineral Oil, Isopropyl Myristate, Cetyl Alcohol, Glycerol Monostearate, Stearic Acid, Glycerin, Propylene Glycol, Ceteareth-20, Carbomer, Aloe Vera, Disodium EDTA, Dimethicone, Petrolatum, Methylparaben, Triethanolamine, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, Propylparaben, Beeswax, Sodium Carbomer, Phenonip, Triethanolamine.

New Hands Free Applicator

(Quad-5 Ball Roller)

Long Lasting and Soothing Deep Penetrating Action

If swallowed, get medical help or contact Poison Control Center right away

Topical analgesic

Capsaicin 0.0375%

Lidocaine 4%

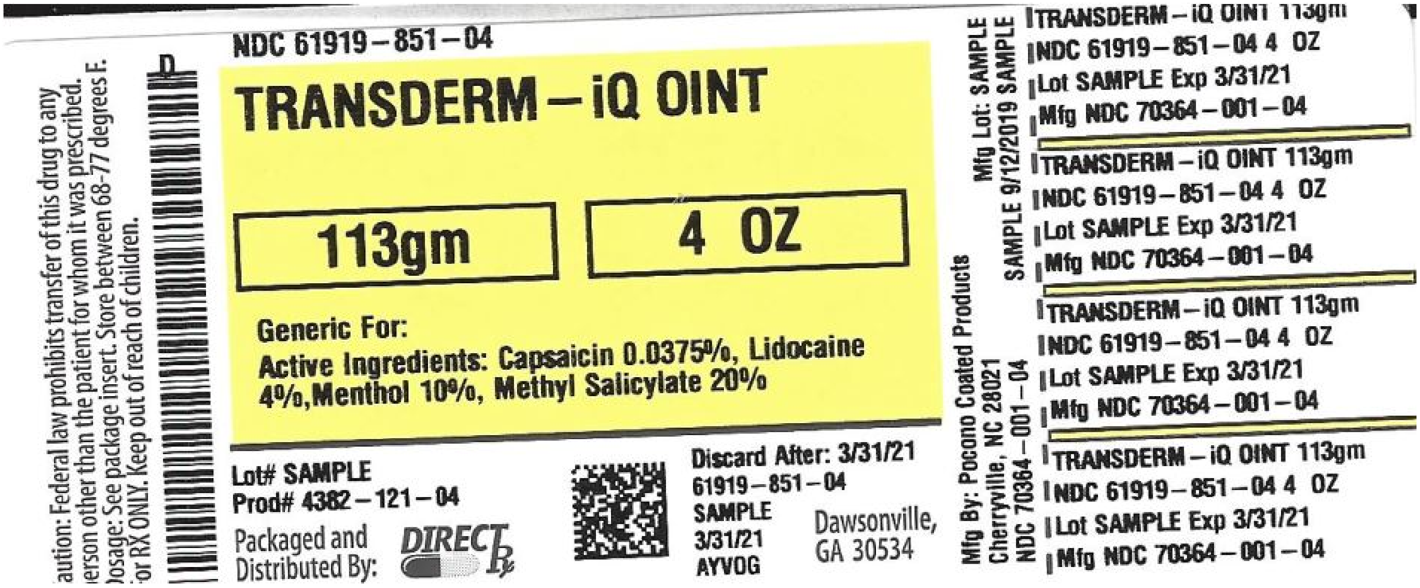
Menthol 10%

Methyl Salicylate 20%

Temporary relief of minor aches and pains of muscles and joints associated with:• simple backache • arthritis • muscle strains • sprains • bruises

Adults 18 years and children 12 years and older:

apply product directly to affected area
product may be used as necessary, but should not be used more than four times per day
wash hands immediately afterwards.



TRANSDERM-IQ

transderm-iq ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-851(NDC:70364-001)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.0375 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	20 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-851-04	113 g in 1 TUBE; Type 0: Not a Combination Product	07/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/25/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(61919-851)

Revised: 9/2019 Direct_Rx