

Attachment A

26TH EDITION - 2006 - APPROVED DRUG PRODUCTS LIST

OTC DRUG PRODUCT LIST

4-9 (of 15)

INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION

NOVOLIN N

NOVO NORDISK INC 100 UNITS/ML

N19959 001 Jul 01, 1991

INSULIN ZINC SUSP EXTENDED RECOMBINANT HUMAN

INJECTABLE; INJECTION

HUMULIN U

+ LILLY 100 UNITS/ML

N19571 002 Jun 10, 1987

INSULIN ZINC SUSP PURIFIED PORK

INJECTABLE; INJECTION

LENTE ILETIN II (PORK)

+ LILLY 100 UNITS/ML

N18347 001

INSULIN ZINC SUSP RECOMBINANT HUMAN

INJECTABLE; INJECTION

HUMULIN L

+ LILLY 100 UNITS/ML

N19377 002 Sep 30, 1985

NOVOLIN L

NOVO NORDISK INC 100 UNITS/ML

N19965 001 Jun 25, 1991

KETOCONAZOLE

SHAMPOO; TOPICAL

NIZORAL A-D

+ MCNEIL CONS SPECLT 1%

N20310 001 Oct 10, 1997

KETOPROFEN

TABLET; ORAL

ACTRON

BAYER 12.5MG

N20499 001 Oct 06, 1995

ORUDIS KT

+ WYETH CONS 12.5MG

N20429 001 Oct 06, 1995

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

LOPERAMIDE HYDROCHLORIDE

BANNER PHARMACAPS 1MG

N21855 001 Aug 04, 2005

+ 2MG

N21855 002 Aug 04, 2005

SOLUTION; ORAL

IMODIUM A-D

+ MCNEIL 1MG/5ML

N19487 001 Mar 01, 1988

+ 1MG/7.5ML

N19487 002 Jul 08, 2004

LOPERAMIDE HYDROCHLORIDE

DURAMED PHARMS BARR 1MG/5ML

N74991 001 Dec 29, 1997

HI TECH PHARMA 1MG/5ML

N74352 001 Nov 17, 1995

MORTON GROVE 1MG/5ML

N74730 001 Aug 28, 1997

PERRIGO 1MG/5ML

N73243 001 Jan 21, 1992

ROXANE 1MG/5ML

N73079 001 Apr 30, 1992

TEVA 1MG/5ML

N73478 001 Jun 23, 1995

TABLET, CHEWABLE; ORAL

IMODIUM A-D

+ MCNEIL 2MG

N20448 001 Jul 24, 1997

TABLET; ORAL

IMODIUM A-D

+ MCNEIL 2MG

N19860 001 Nov 22, 1989

LOPERAMIDE HYDROCHLORIDE

LEINER 2MG

N73254 001 Jul 30, 1993

LNK 2MG

N76497 001 Jun 10, 2003

OHM LABS 2MG

N74091 001 Dec 10, 1992

PERRIGO 2MG

N75232 001 Jan 06, 2000

Search results from the "OB_OTC" table for query on "019860."

Active Ingredient:	LOPERAMIDE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	IMODIUM A-D
Applicant:	MCNEIL
Strength:	2MG
Application Number:	019860
Product Number:	001
Approval Date:	Nov 22, 1989
Reference Listed Drug	Yes
RX/OTC/DISCN:	OTC
Patent and Exclusivity Info for this product:	View

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through April, 2006

Patent and Generic Drug Product Data Last Updated: June 14, 2006

Patent and Exclusivity Search Results from query on Appl No 019860 Product 001 in the OB_OTC list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

There is no unexpired exclusivity for this product.

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