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EDA Home³ Drug Databases⁴ Orange Book⁵ Orange Book⁵ Products with Therapeutic Equivalence Evaluations Search results from the "OB_Rx" table for query on "020272."

Active Ingredient:

Dosage Form; Route: Proprietary Name:

RISPERIDONE TABLET; ORAL **RISPERDAL**

Applicant:

JANSSEN PHARMS

Strength:

1MG

Application Number: Product Number:

N020272

001

Approval Date:

Dec 29, 1993

Reference Listed Drug RX/OTC/DISCN:

Yes RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

RISPERIDONE

Dosage Form; Route:

TABLET; ORAL

Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

2MG

Application Number:

N020272

Product Number:

002

Approval Date:

Dec 29, 1993

Reference Listed Drug RX/OTC/DISCN:

No

RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

RISPERIDONE

Dosage Form; Route:

TABLET; ORAL

Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

3MG

Application Number:

N020272

Product Number:

003

Approval Date:

Dec 29, 1993 No

Reference Listed Drug RX/OTC/DISCN:

RX

TE Code:

AΒ

Patent and Exclusivity Info for this product: View

Active Ingredient:

RISPERIDONE

Dosage Form; Route:

TABLET; ORAL

http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=020272&TAB... 5/31/2016



Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

4MG

Application Number:

N020272

Product Number:

004

Approval Date:

Dec 29, 1993

Reference Listed Drug RX/OTC/DISCN:

No

RX

TE Code:

AΒ

Patent and Exclusivity Info for this product: View

Active Ingredient:

RISPERIDONE

Dosage Form; Route:

TABLET; ORAL

Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

0.5MG

Application Number:

N020272

Product Number:

Approval Date:

007

Reference Listed Drug

Jan 27, 1999

RX/OTC/DISCN:

No RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

RISPERIDONE

Dosage Form; Route:

TABLET; ORAL

Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

0.25MG

Application Number:

N020272

Product Number:

800

Approval Date:

May 10, 1999

Reference Listed Drug

No

RX/OTC/DISCN:

RX

TE Code:

Patent and Exclusivity Info for this product: View

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Active Ingredient:

RISPERIDONE

Dosage Form; Route:

SOLUTION; ORAL

Proprietary Name:

RISPERDAL

Applicant:

JANSSEN PHARMS

Strength:

1MG/ML

Application Number:

N020588

Jun 10, 1996

Product Number:

001

Approval Date:

001

Reference Listed Drug

Yes

RX/OTC/DISCN:

RX

TE Code:

AA

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 2016

Patent and Generic Drug Product Data Last Updated May 31, 2016

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