# RUGBY MECLIZINE HCL, 12.5 MG EACH ANTIEMETIC- meclizine hcl tablet NuCare Pharmaceuticals, Inc.

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.

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## **MECLIZINE HCl, USP 12.5 mg CAPLETS**

#### **Drug Facts**

## Active ingredient (in each caplet)

Meclizine HCl, USP 12.5 mg

### **Purpose**

Antiemetic

#### Uses

prevents and treats nausea, vomiting or dizziness due to motion sickness

# Warnings

**Do not use** in children under 12 years of age unless directed by a doctor

# Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

# When using this product

- Imay cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

**If pregnant or breast-feeding,** ask a health professional before use.

### Keep out of reach of children.

In case of overdose, get medical help or contact the poison control center immediately.

#### Directions

- Dosage should be taken one hour before travel starts.
- **Adults and children 12 years of age and older:** take 2-4 caplets once daily, or as directed by a doctor
- **Children under 12 years:** do not give this product to children under 12 years of age unless directed by a doctor

#### Other information

- Each Caplet Contains: Calcium 25 mg
- store at room temperature in a dry place
- Keep lid tightly closed

## **Inactive ingredients**

croscarmellose sodium, dicalcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose,

silicon dioxide, sodium sulfate, stearic acid.

Questions or comments?

call **1-800-645-2158** 

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DROKEN OK MISSING

Distributed by: **Rugby Laboratories** 

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# **RUGBY MECLIZINE HCL, 12.5 MG EACH ANTIEMETIC**

meclizine hcl tablet

| Product Information     |                |                    |                               |  |
|-------------------------|----------------|--------------------|-------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68071-3063(NDC:0536-1017) |  |
| Route of Administration | ORAL           |                    |                               |  |

| Active Ingredient/Active Moiety  |                         |          |  |  |
|--|-------------------------|----------|--|--|
| Ingredient Name  | Basis of Strength       | Strength |  |  |
| MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | MECLIZINE HYDROCHLORIDE | 12.5 mg  |  |  |

| Inactive Ingredients                                      |          |  |  |  |
|---|----------|--|--|--|
| Ingredient Name   | Strength |  |  |  |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)                  |          |  |  |  |
| CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP) |          |  |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6 B0)                     |          |  |  |  |

| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) |  |
|---|--|
| SILICON DIO XIDE (UNII: ETJ7Z6XBU4)             |  |
| SODIUM SULFATE (UNII: 0 YPR65R21J)              |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)                 |  |

| Product Characteristics |   |              |          |  |
|-------------------------|---|--------------|----------|--|
| Color                   | white   | Score        | 2 pieces |  |
| Shape                   | CAPSULE (modified capsule shaped uncoated tablet with bisect) | Size         | 3mm      |  |
| Flavor                  |   | Imprint Code | 19 G     |  |
| Contains                |   |              |          |  |

| F | Packaging        |   |                             |                           |
|---|------------------|---|-----------------------------|---------------------------|
| # | Item Code        | Package Description                               | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 | NDC:68071-3063-2 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 03/10/2017                  |                           |
| 2 | NDC:68071-3063-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 03/10/2017                  |                           |
| 3 | NDC:68071-3063-6 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 03/10/2017                  |                           |
| 4 | NDC:68071-3063-9 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 03/10/2017                  |                           |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final   | part336                                  | 03/07/2014           |                    |
|                       |  |                      |                    |

# **Labeler -** NuCare Pharmaceuticals, Inc. (010632300)

| Establishment                |         |           |                     |  |
|------------------------------|---------|-----------|---------------------|--|
| Name                         | Address | ID/FEI    | Business Operations |  |
| NuCare Pharmaceuticals, Inc. |         | 010632300 | repack(68071-3063)  |  |

Revised: 2/2021 NuCare Pharmaceuticals, Inc.