**MECLIZINE- meclizine hcl 25mg tablet, chewable**
**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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**Drug Facts**

**Active ingredient (in each tablet)**

Meclizine HCl 25mg

**Purpose**

Antiemetic

**Uses**

prevents and treats nausea, vomiting or dizziness associated with motion sickness

**Warnings**

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

**Do not take unless directed by a doctor if you have**

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

**Do not take if you are** taking sedatives or tranquilizers, without first consulting your doctor.

**When using this product**

- do not exceed recommended dosage
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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 a Poison Control Center right away.

**Directions**

- doage should be taken 1 hour before travel starts

| | |
|---|---|
| Adults and children 12 years and over | take 1 or 2 tablets once daily or as directed by doctor |

**Other information**

- **Tamper Evident:** do not use if safety seal under cap is broken or missing
- store at room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**

Croscarmellose sodium, dextrose, FD&C Red#40, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium saccharine, stearic acid

**Questions?**

**Adverse drug event call** (800) 687-0176 (M - F, 8AM - 4PM EST).


## MECLIZINE

meclizine hcl 25mg tablet, chewable

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68071-4584(NDC:66424-387) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MECLIZINE HYDROCHLORIDE** (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | MECLIZINE HYDROCHLORIDE | 25 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **DEXTROSE** (UNII: IY9XDZ35W2) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |

| | |
|---|---|
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | pink (LIGHT PINK COLOR) | **Score** | 2 pieces |
| **Shape** | ROUND (ROUND TABLET) | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | PH051 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:68071-4584-2 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 04/04/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part336 | 02/01/2018 | |

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

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| NUCARE PHARMACEUTICALS INC | | 010632300 | repack(68071-4584) |

Revised: 4/2019 NuCare Pharmaceuticals,Inc.