

MECLIZINE HCL- meclizine hcl 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.

TRAVEL SICKNESS CHEWABLE TABLETS

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl USP 25 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

- may 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:** Chew 1-2 tablets 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

- Phenylketonurics: Contains Phenylalanine 0.28 mg per tablet
- Store at room temperature in a dry place
- Keep lid tightly closed

Inactive ingredients

aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.

Questions or comments?

call 1-800-645-2158

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

Distributed by: Rugby Laboratories

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152



Patent Instructions

Chew _____ every _____ hours
_____ times a day.

68071221903-30*000000*000000

NDC: 68071-2219-3

Meclizine HCl 25mg

#30 Chewtabs

Each chewtab contains: Meclizine HCl, USP 25mg..... Antiemetic
Phenylketonurics: Contains Phenylalanine 0.28 mg per tablet 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, may 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 Round Pink Scored Chewtab Debossed: "21 G" on the
scored side

Product #: P1763030

Meclizine HCl 25mg
Lot: 000000 NDC: 68071-2219-03
MFR NDC: 0536-1018-01 Exp.: 00-00
Serial# 00000000002

Meclizine HCl 25mg
Lot: 000000 NDC: 68071-2219-03
MFR NDC: 0536-1018-01 Exp.: 00-00
Serial# 00000000002

GTIN 00368071221930
Serial# 00000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

MECLIZINE HCL

meclizine hcl tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|-------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68071-2219(NDC:0536-1018) |
| 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 |
|--|----------|
| ASPARTAME (UNII: Z0H242BBR1) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DEXTROSE (UNII: IY9XDZ35W2) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM SULFATE (UNII: 0YPR65R21J) | |

| SUCROSE (UNII: C151H8M554) | | | | |
|---|--|---|----------------------|--------------------|
| TRICALCIUM PHOSPHATE (UNII: K4C08XP666) | | | | |
| Product Characteristics | | | | |
| Color | pink | Score | 2 pieces | |
| Shape | ROUND (Biconvex Uncoated Tablet with Bisect) | Size | 8mm | |
| Flavor | | Imprint Code | 21G | |
| Contains | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:68071-2219-3 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/20/2020 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part336 | 08/19/2014 | | |

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

| Establishment | | | |
|------------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| NuCare Pharmaceuticals, Inc. | | 010632300 | repack(68071-2219) |

Revised: 7/2020

NuCare Pharmaceuticals, Inc.