**MECLIZINE HCL 25 MG- meclizine hcl 25 mg tablet, chewable**
**RedPharm Drug, 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.*

---

## 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

WARNINGS

## DO NOT USE

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

## ASK 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 DOCTOR/PHARMACIST

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

## PREGNANCY OR BREAST FEEDING

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

## KEEP OUT OF REACH OF CHILDREN

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

store at room temperature

## OTHER SAFETY INFORMATION

Phenylketonurics: Contains phenylalanine 0.28 mg per tablet
Do not use if imprinted safety seal under cap is broken or missing

## 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?

If you have any questions or comments or to report an adverse event, please contact (800) 795-9775.

## SPL UNCLASSIFIED SECTION

## WHEN USING

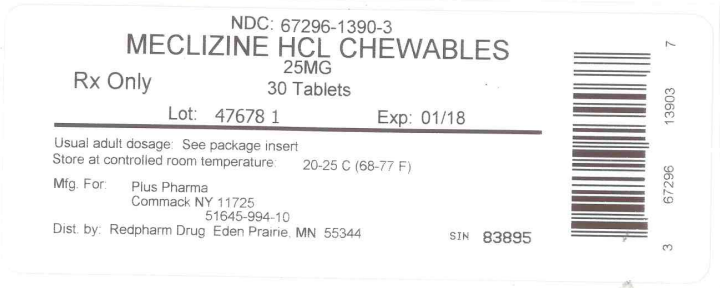
When using this product

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

## PURPOSE

Antiemetic

## PRINCIPAL DISPLAY PANEL




# MECLIZINE HCL 25 MG

meclizine hcl 25 mg tablet, chewable

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67296-1390(NDC:51645-994) |
| **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) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **TRICALCIUM PHOSPHATE** (UNII: K4C08XP666) | |
| **ASPARTAME** (UNII: Z0H242BBR1) | |
| **SUCROSE** (UNII: C151H8M554) | |
| **DEXTROSE** (UNII: IY9XDZ35W2) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM SULFATE** (UNII: 0YPR65R21J) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | pink (uncoated) | **Score** | 2 pieces |
| **Shape** | ROUND (bioconvex) | **Size** | 8mm |
| **Flavor** | RASPBERRY | **Imprint Code** | 21G |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:67296-1390-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 10/15/2015 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part336 | 10/15/2015 | |

**Labeler -** RedPharm Drug, Inc. (828374897)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| RedPharm Drug, Inc. | | 828374897 | repack(67296-1390) , relabel(67296-1390) |

Revised: 1/2020 RedPharm Drug, Inc.