

**MECLIZINE HCL- meclizine hcl 25mg chewable tablets tablet, chewable
Aphena Pharma Solutions - Tennessee, LLC**

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.

Motion Sickness

Active ingredient

Meclizine Hydrochloride 25 mg

Purpose

Antiemetic

Uses

For the prevention and treatment of nausea, vomiting or dizziness associated with motion sickness. For other uses consult your doctor

Warnings

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

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Directions

**take dose one hour before travel starts
tablets can be chewed or swallowed whole with water**

adults & children 12 years and over:

- take 1-2 tablets once daily

children under 12 years:

- ask a doctor

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

OTHER INFORMATION

Phenylketonurics:

each tablet contains:

phenylalanine 0.28 mg

store at room temperature 15 - 30 °C

Questions or Comments

Call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

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

Inactive ingredients

Aspartame, compressible sugar, croscarmellose sodium, dextrose, FD&C red 40 (a-lake), magnesium stearate, microcrystalline cellulose, raspberry flavor

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

| Count | 25 mg |
|-------|---------------|
| 30 | 71610-0528-30 |
| 90 | 71610-0528-60 |

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:

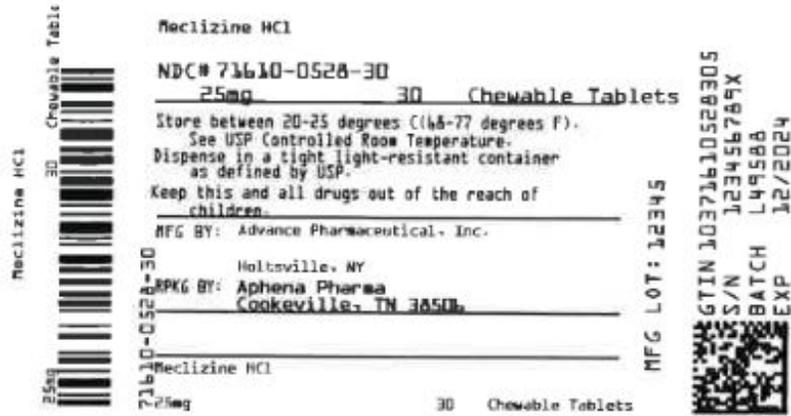


Cookeville, TN 38506

20210415JH

PRINCIPAL DISPLAY PANEL - 25 mg

NDC 71610-528 - Meclizine HCl 25 mg Chewable Tablets



MECLIZINE HCL

meclizine hcl 25mg chewable tablets tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71610-528(NDC:54738-025) |
| 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) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| DEXTROSE (UNII: IY9XDZ35W2) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| RASPBERRY (UNII: 4N14V5R27W) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SUCROSE (UNII: C151H8M554) | |

Product Characteristics

| | | | |
|-----------------|-----------|---------------------|----------|
| Color | red | Score | 2 pieces |
| Shape | ROUND | Size | 8mm |
| Flavor | RASPBERRY | Imprint Code | AP;115 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71610-528-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 03/04/2021 | |
| 2 | NDC:71610-528-60 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 03/04/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part336 | 05/01/2015 | |

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---------------------|
| Aphenia Pharma Solutions - Tennessee, LLC | | 128385585 | REPACK(71610-528) |

Revised: 4/2021

Aphenia Pharma Solutions - Tennessee, LLC