

**MECLIZINE HYDORCHLORIDE- meclizine hydrochloride - chewable tablet, chewable  
Bellegrove Medical Supply, 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 Hydrochloride - Chewable**

Do not use

- for children under 12 years of age unless directed by a physician
- for frequent or prolonged use except under the advice of a physician

Ask a doctor before use if you have

breathing problems such as emphysema, asthma or pulmonary disease  
glaucoma

if you are

- taking sedatives or tranquilizers

When using this product

drowsiness may occur

alcohol, sedatives and tranquilizers may increase the drowsiness effect

consult with your physician

avoid alcoholic beverages while taking this product

use caution when driving a motor vehicle or operating machinery

Do not exceed recommended dosage

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 Poison Control Center right away

Other information

- store at room temperature 59-86 degrees F (15-30 degreesC)
- tamper-evident sealed packets
- do not use any opened or torn packets

**DOSAGE AND ADMINISTRATION**

Directions

do not use more than directed

to prevent motion sickness, take the first dose one hour before starting activity

Adults and children (12 years and older)

1 to 2 tablets once daily or as directed by a Physician

Do not exceed 2 tablets in 24 hours

Children under 12 years of age: Do not give to children under 12 years of age

**INDICATION AND USAGE**

For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness.

# OTC-KEEP OUT OF REACH OF CHILDREN

Do not use

- for children under 12 years of age unless directed by a physician

Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away

## PURPOSE

When using this product

drowsiness may occur

alcohol, sedatives and tranquilizers may increase the drowsiness effect

consult with your physician

avoid alcoholic beverages while taking this product

use caution when driving a motor vehicle or operating machinery

## Active ingredients

anhydrous lactose

## Inactive ingredients

Anhydrous Lactose, Colloidal Silicon Dioxide, Croscopovidone, Dextrose, FD&C red #40 aluminum lake, magnesium stearate, Microcrystalline Cellulose, Modified Corn Starch, Propylene Glycol, Raspberry Flavor, Silicon Dioxide, Sodium Saccharin, Stearic Acid, Talc and Vanilla Flavor.

## Package label



## MECLIZINE HYDORCHLORIDE

meclizine hydrochloride - chewable tablet, chewable

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59961-125 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>   | <b>Basis of Strength</b> | <b>Strength</b> |
|--|--------------------------|-----------------|
| Meclizine hydrochloride (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | Meclizine hydrochloride  | 25 mg           |

**Inactive Ingredients**

| <b>Ingredient Name</b>               | <b>Strength</b> |
|--------------------------------------|-----------------|
| anhydrous lactose (UNII: 3SY5LH9PMK) | 1 mg            |

**Product Characteristics**

|                 |           |                     |          |
|-----------------|-----------|---------------------|----------|
| <b>Color</b>    | pink      | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND     | <b>Size</b>         | 10mm     |
| <b>Flavor</b>   | RASPBERRY | <b>Imprint Code</b> |          |
| <b>Contains</b> |           |                     |          |

**Packaging**

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:59961-125-01 | 2 in 1 PACKAGE                                      | 01/01/2012           |                    |
| 1 | NDC:59961-125-02 | 500 in 1 BOX; Type 1: Convenience Kit of Co-Package |                      |                    |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final       | part336   | 01/01/2012                  |                           |

**Labeler** - Bellegrove Medical Supply, Inc. (141647094)**Registrant** - Bellegrove Medical Supply, Inc. (141647094)**Establishment**

| <b>Name</b>      | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>  |
|------------------|----------------|---------------|---|
| Future Pak, Ltd. |                | 087737672     | api manufacture(59961-125) , pack(59961-125) , relabel(59961-125) |