MECLIZINE- meclizine hcl 12.5 mg tablet Pharbest 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.

Drug Facts

Active ingredient (in each caplet)

Meclizine HCl 12.5mg

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

• dosage should be taken 1 hour before travel starts

| Adults and children 12 | take 2 or 4 caplets once daily or as |
|------------------------|--------------------------------------|
| years and over | 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, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions?

Adverse drug event call (866) 562-2756 (M - F, 8AM - 4PM EST).

PHARBEST

NDC 16103-0386-11

Manufactured in the USA

Motion Sickness Relief

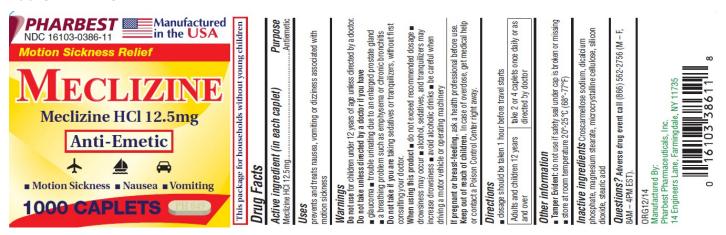
MECLIZINE

Meclizine HCl 12.5mg

Anti-Emetic

• Motion Sickness • Nausea • Vomiting

100 CAPLETS



MECLIZINE

meclizine hcl 12.5 mg tablet

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:16103-386 | |
| Route of Administration | ORAL | | | |

| Active Ingredient/Active Moiety | | | | |
|---------------------------------|--|-------------------------|----------|--|
| | Ingredient Name | Basis of Strength | Strength | |
| | MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | MECLIZINE HYDROCHLORIDE | 12.5 mg | |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | | | |
| CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | | | |

| Product Characteristics | | | | |
|-------------------------|---------------------------------|--------------|----------|--|
| Color | white | Score | no score | |
| Shape | CAPSULE (CAPSULE SHAPED TABLET) | Size | 13mm | |
| Flavor | | Imprint Code | PH0 49 | |
| Contains | | | | |

| ı | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | | NDC:16103-386- 08 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 2/0 1/20 18 | |
| | 2 | NDC:16103-386- 11 | 1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 2/0 1/20 18 | |

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

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

| Establishment | | | |
|--------------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Pharbest Pharmaceuticals, Inc. | | 557054835 | manufacture(16103-386), pack(16103-386), analysis(16103-386) |

Revised: 2/2018 Pharbest Pharmaceuticals, Inc.