MECLIZINE HCL- meclizine hcl 25mg chewable tablets tablet, chewable
Richmond 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.

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 elarged 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 increse drowsiness
- be careful when driving a moor 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 temparature 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

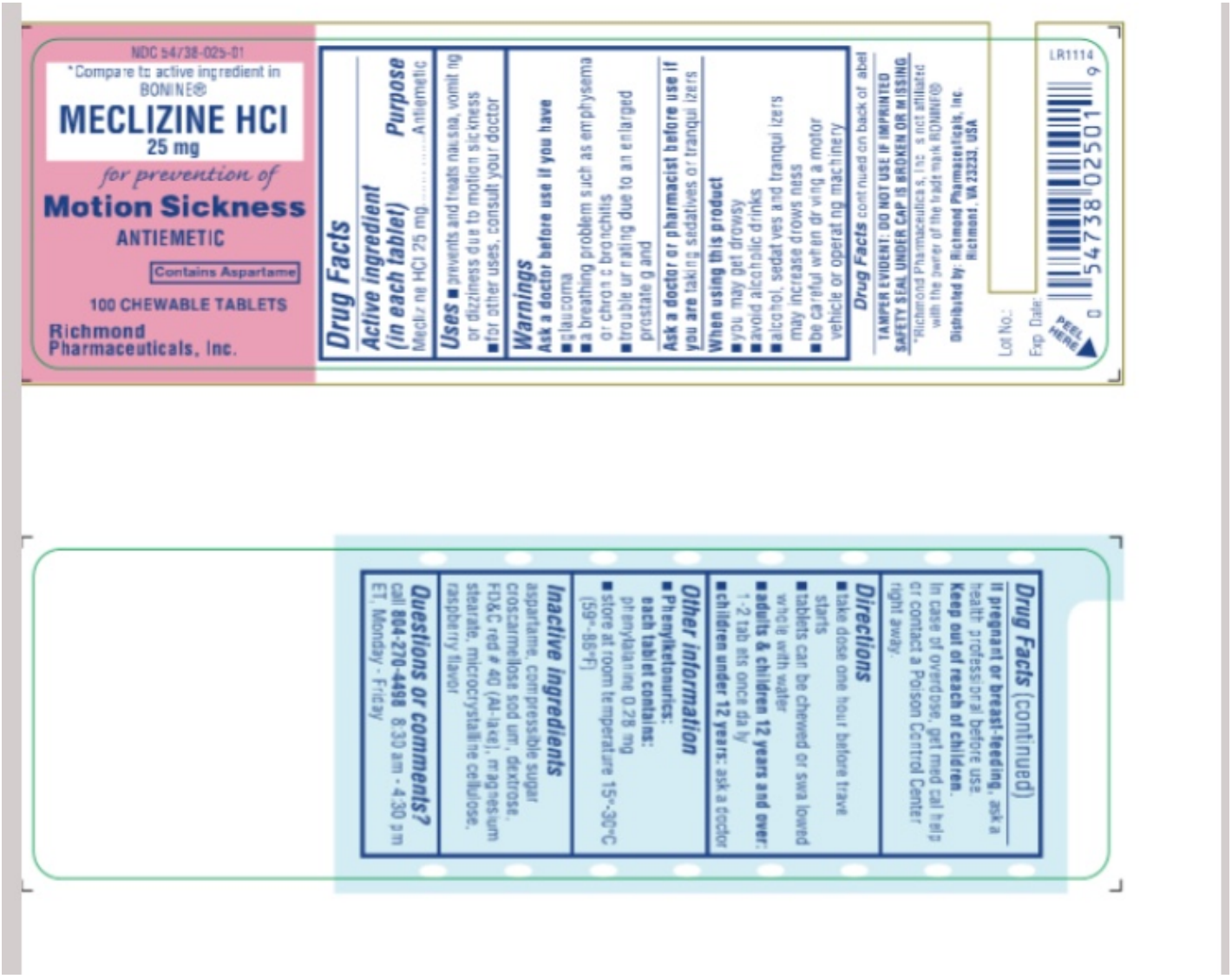
Inactive ingredients

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

Package/Label Principal Display Panel

NDC : 54738-025-01- 100 CHEW TABS

NDC : 54738-025-03- 1000 CHEW TABS



MECLIZINE HCL

meclizine hcl 25mg chewable tablets tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:54738-025-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
2	NDC:54738-025-03	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

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

Labeler - Richmond Pharmaceuticals, Inc. (043569607)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-025)

Revised: 10/2017 Richmond Pharmaceuticals, Inc.