

## **MOTION SICKNESS RELIEF- dimenhydrinate tablet**

**Valu Merchandisers Company**

*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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### **Best Choice 44-198**

#### ***Active ingredient (in each tablet)***

Dimenhydrinate 50 mg

#### ***Purpose***

Antiemetic

#### ***Uses***

for prevention and treatment of these symptoms associated with motion sickness:

- nausea
- vomiting
- dizziness

#### ***Warnings***

##### **Do not use**

for children under 2 years of age unless directed by a doctor.

##### **Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

##### **Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

##### **When using this product**

- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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 (1-800-222-1222) right away.

#### ***Directions***

- to prevent motion sickness, the first dose should be taken one-half to one hour before starting activity

adults and children 12 years and over	1 to 2 tablets every 4-6 hours; do not exceed 8 tablets in 24 hours, or as directed by a doctor
children 6 to under 12 years	½ to 1 tablet every 6-8 hours; do not exceed 3 tablets in 24 hours, or as directed by a doctor
children 2 to under 6 years	½ tablet every 6-8 hours; do not exceed 1½ tablets in 24 hours, or as directed by a doctor

#### ***Other information***

- **each tablet contains:** calcium 35 mg
- see end flap for expiration date and lot number
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture

#### ***Inactive ingredients***

croscarmellose sodium, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

#### ***Questions or comments?***

**1-800-426-9391**

#### ***Principal display panel***

**Best  
Choice®**

COMPARE TO THE ACTIVE INGREDIENT IN DRAMAMINE® ORIGINAL FORMULA\*

**Motion Sickness Relief**

**Dimenhydrinate 50 mg  
Antiemetic**

Prevents Nausea, Vomiting & Dizziness  
for Children & Adults

Actual Size

**12 Tablets**

**PROUDLY DISTRIBUTED BY:  
VALU MERCHANDISERS, CO.  
5000 KANSAS AVE  
KANSAS CITY, KS 66106**

The image shows a blister pack for 'Best Choice Motion Sickness Relief'. The pack is primarily blue and yellow. At the top (which would be the bottom of the pack), it says 'COMPARE TO THE ACTIVE INGREDIENT IN DRAMAMINE® ORIGINAL FORMULA\*'. Below this, in large white letters on a blue background, is 'Motion Sickness Relief'. To the right of this text is a circular logo with 'Best Choice®'. Below the main title, it says 'Dimenhydrinate 50 mg Antiemetic Prevents Nausea, Vomiting & Dizziness for Children & Adults'. To the right of this, it says 'Actual Size' above a single white tablet, and '12 TABLETS' below it. The pack is divided into several sections for text. The top section (on the left side of the image) contains 'Drug Facts', 'Purpose', 'Warnings', and 'Drug Facts (continued)'. The middle section (on the right side) contains 'Drug Facts (continued)', 'Inactive ingredients', and 'Questions or comments?'. The bottom section (on the left side) contains 'Directions', 'Other information', and 'Drug Facts (continued)'. The bottom right section (on the right side) contains 'Drug Facts (continued)'. The text in these sections is oriented upside down relative to each other. On the far left, there is a barcode and the text 'No Print/No Varnish Lot & Exp Date'. On the far right, there is a vertical strip with 'Best Choice, 100% Guaranteed' and 'www.bestchoicebrand.com'. At the very bottom (which would be the top of the pack), there is a small text block: 'PROUDLY DISTRIBUTED BY: VALU MERCHANTISERS, CO. 5000 KANSAS AVE KANSAS CITY, KS 66106'. A warning label on the right side says: 'TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING'. A small text block at the bottom left says: 'B-2115-198-02-R OR6051819802'. A small text block at the bottom right says: '50844 OR6051819802'.

### Best Choice 44-198

## MOTION SICKNESS RELIEF

dimenhydrinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-198
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMENHYDRINATE (UNII: JB937PER5C) (DIPHENHYDRAMINE - UNII:8GTS82S83M, CHLORTHEOPHYLLINE - UNII:GE2UA340FM)	DIMENHYDRINATE	50 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	44;198
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-198-02	2 in 1 CARTON	02/15/20 19	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	02/15/20 19	

**Labeler** - Valu Merchandisers Company (868703513)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(63941-198)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(63941-198)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(63941-198)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(63941-198)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(63941-198)

Revised: 12/2019

Valu Merchandisers Company