#### ANTIVERT - meclizine hcl tablet ANTIVERT - meclizine hcl tablet, chewable Casper Pharma LLC

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HGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use ANTIVERT <sup>®</sup> safely and effectively. See full prescribing information for ANTIVERT <sup>®</sup> .					
ANTIVERT <sup>®</sup> (meclizine HCI) tablets, for oral use ANTIVERT <sup>®</sup> (meclizine HCI) chewable tablets, for oral use Initial U.S. Approval: 1957					
INDICATIONS AND USAGE					
ANTIVERT <sup>®</sup> is indicated for the treatment of vertigo associated with diseases affecting the vestibular system in adults (1).					
DOSAGE AND ADMINISTRATION					
<ul> <li>Recommended dosage: 25 mg to 100 mg daily, in divided doses (2.1).</li> <li>Tablets: Swallow whole (2.2).</li> </ul>					
<ul> <li>Chewable Tablets: Must be chewed or crushed before swallowing; do not swallow whole (2.2).</li> </ul>					
DOSAGE FORMS AND STRENGTHS					
<ul> <li>Tablets: 12.5 mg, 25 mg, and 50 mg (3).</li> <li>Chewable Tablets: 25 mg (3).</li> </ul>					
CONTRAINDICATIONS					
ANTIVERT <sup>®</sup> is contraindicated in patients with hypersensitivity to meclizine or any of the inactive ingredients (4).					
WARNINGS AND PRECAUTIONS					
<ul> <li>May cause drowsiness: Use caution when driving a car or operating dangerous machinery (5.1).</li> <li>Potential anticholinergic action: this drug should be prescribed with care to patients with a history of asthma, glaucoma, or enlargement of the prostate gland (5.2).</li> </ul>					
ADVERSE REACTIONS					
Common adverse reactions are anaphylactic reaction, drowsiness, dry mouth, headache, fatigue, and vomiting. On rare occasions blurred vision has been reported (6).					
To report SUSPECTED ADVERSE REACTIONS, contact Casper Pharma LLC at 1-844-5-CASPER (1-844-522-7737) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.					
DRUG INTERACTIONS					
• Coadministration of ANTIVERT <sup>®</sup> with other CNS depressants, including alcohol, may result in increased CNS depression (7.1).					
• CYP2D6 inhibitors: As meclizine is metabolized by CYP2D6, there is a potential for drug-drug interactions between ANTIVERT <sup>®</sup> and CYP2D6 inhibitors (7.2).					
See 17 for PATIENT COUNSELING INFORMATION.					

**Revised: 10/2022** 

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\* Sections or subsections omitted from the full prescribing information are not listed.

# FULL PRESCRIBING INFORMATION

# **1 INDICATIONS AND USAGE**

ANTIVERT $^{\mbox{\tiny B}}$  is indicated for the treatment of vertigo associated with diseases affecting the vestibular system in adults.

# **2 DOSAGE AND ADMINISTRATION**

### 2.1 Recommended Dosage

The recommended dosage is 25 mg to 100 mg daily administered orally, in divided doses, depending upon clinical response.

# 2.2 Administration Instructions

 $\underline{\text{Tablets}}$  ANTIVERT  $^{\textcircled{B}}$  tablets must be swallowed whole.

Chewable Tablets

ANTIVERT<sup>®</sup> chewable tablets must be chewed or crushed completely before swallowing. Do not swallow chewable tablets whole.

# **3 DOSAGE FORMS AND STRENGTHS**

Tablets

• 12.5 mg: oval-shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "34" and one white to off white layer debossed with "L".

• 25 mg: oval-shaped, biconvex, two-layered tablet, one yellow to pale yellow layer debossed with "49" and one white to off white layer debossed with "L".

• 50 mg: oval-shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "50" and one yellow to pale yellow layer and debossed with "L".

Chewable Tablets

• 25 mg: pink colored round tablets debossed with "M 25" on one side and break line on other side.

### **4 CONTRAINDICATIONS**

ANTIVERT<sup>®</sup> is contraindicated in patients with a hypersensitivity to meclizine or any of the inactive ingredients [*see Adverse Reactions (6) and Description (11)*].

### **5 WARNINGS AND PRECAUTIONS**

### 5.1 Drowsiness

Since drowsiness may occur with use of ANTIVERT<sup>®</sup>, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Patients should avoid alcoholic beverages while taking ANTIVERT<sup>®</sup>[see Drug Interactions (7.1)].

### 5.2 Concurrent Medical Conditions

Because of its potential anticholinergic action, ANTIVERT<sup>®</sup> should be used with caution in patients with asthma, glaucoma, or enlargement of the prostate gland.

# 6 ADVERSE REACTIONS

The following adverse reactions associated with the use of ANTIVERT<sup>®</sup> were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylactic reaction, drowsiness, dry mouth, headache, fatigue, and vomiting. On rare occasions blurred vision has been reported.

### **7 DRUG INTERACTIONS**

# 7.1 CNS Depressants

There may be increased CNS depression when ANTIVERT<sup>®</sup> is administered concurrently with other CNS depressants, including alcohol [*see Warnings and Precautions (5.1)*].

### 7.2 CYP2D6 Inhibitors

Based on *in-vitro* evaluation, meclizine is metabolized by CYP2D6. Therefore, there is a possibility for a drug interaction between ANTIVERT<sup>®</sup> and CYP2D6 inhibitors. Therefore, monitor for adverse reactions and clinical effect accordingly.

# **8 USE IN SPECIFIC POPULATIONS**

### 8.1 Pregnancy

#### <u>Risk Summary</u>

Data from epidemiological studies have not generally indicated a drug-associated risk of major birth defects with meclizine during pregnancy. However, in a published study, an increased incidence of fetal malformations was observed following oral administration of meclizine to pregnant rats during the period of organogenesis, at doses similar to those used clinically.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

#### <u>Data</u>

#### Human Data

Epidemiological studies reporting on pregnancies exposed to meclizine have not identified an association between the use of meclizine during pregnancy and an increased risk of major birth defects.

#### Animal Data

In a published study, oral administration of meclizine (25-250 mg/kg) to pregnant rats during the period of organogenesis resulted in a high incidence of fetal malformations. These effects occurred at doses as low as 25 mg/kg, which is approximately 2 times the maximum recommended human dose (100 mg) on a body surface area (mg/m2) basis.

### 8.2 Lactation

#### <u>Risk Summary</u>

There are no data on the presence of meclizine in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ANTIVERT<sup>®</sup> and any potential adverse effects on the breastfed infant from ANTIVERT<sup>®</sup> or from the underlying maternal condition.

# 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### 8.5 Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

### 8.6 Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics of meclizine has not been evaluated. As ANTIVERT<sup>®</sup> undergoes metabolism, hepatic impairment may result in increased systemic exposure of meclizine. Treatment with ANTIVERT<sup>®</sup> should be administered with caution in patients with hepatic impairment.

### 8.7 Renal Impairment

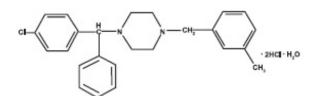
The effect of renal impairment on the pharmacokinetics of meclizine has not been evaluated. Because of a potential for drug/metabolite accumulation, ANTIVERT<sup>®</sup> should be administered with caution in patients with renal impairment and in the elderly, as renal function generally declines with age.

### 8.8 Genetic CYP2D6 Polymorphism

The genetic polymorphism of CYP2D6 that results in poor-, intermediate-, extensive-, and ultrarapid metabolizer phenotypes could contribute to large inter-individual variability in meclizine exposure. Therefore, when ANTIVERT<sup>®</sup> is administered to patients with CYP2D6 polymorphism, monitor for adverse reactions and clinical effect accordingly.

# **11 DESCRIPTION**

ANTIVERT<sup>®</sup> (meclizine HCl), a histamine (H1) receptor antagonist, is a white or slightly yellowish, crystalline powder. It has the following structural formula:



Chemically, ANTIVERT<sup>®</sup> (meclizine HCl) is  $1-(p-chloro-\alpha-phenylbenzyl)-4-(m-methylbenzyl) piperazine dihydrochloride monohydrate.$ 

### <u>Tablets</u>

Inactive ingredients for the tablets are: corn starch; dibasic calcium phosphate; magnesium stearate; polyethylene glycol; sucrose. The 12.5 mg tablets also contain: FD&C Blue # 1. The 25 mg tablets also contain: FD&C Yellow # 6 and D&C Yellow # 10. The 50 mg tablets also contain: FD&C Blue # 1, FD&C Yellow # 6 and D&C Yellow # 10.

Each ANTIVERT<sup>®</sup> (meclizine HCl) 12.5 mg tablet contains 12.5 mg of meclizine dihydrochloride equivalent to 10.53 mg of meclizine free base. Each ANTIVERT<sup>®</sup> (meclizine HCl) 25 mg tablet contains 25 mg of meclizine dihydrochloride equivalent to 21.07 mg of meclizine free base. Each ANTIVERT<sup>®</sup> (meclizine HCl) 50 mg tablet contains 50 mg of meclizine dihydrochloride equivalent to 42.14 mg of meclizine free base.

#### Chewable Tablets

Inactive ingredients for the chewable tablets are: corn starch, colloidal silicon dioxide, FD&C Red # 40, lactose monohydrate, magnesium stearate, raspberry flavor, saccharin sodium, and talc.

Each ANTIVERT<sup>®</sup> (meclizine HCl) 25 mg chewable tablet contains 25 mg of meclizine dihydrochloride equivalent to 21.07 mg of meclizine free base.

### **12 CLINICAL PHARMACOLOGY**

#### 12.1 Mechanism of Action

The precise mechanism by which meclizine exerts its therapeutic effect is unknown but is presumed to involve antagonism of the histamine H1 receptor.

#### **12.2 Pharmacodynamics**

There are no relevant pharmacodynamic data regarding meclizine.

#### **12.3 Pharmacokinetics**

The available pharmacokinetic information for meclizine following oral administration has been summarized from published literature.

#### <u>Absorption</u>

Meclizine is absorbed after oral administration with maximum plasma concentrations reaching at a median  $T_{max}$  value of 3 hours post-dose (range: 1.5 to 6 hours) for the tablet dosage form.

#### <u>Distribution</u>

Drug distribution characteristics for meclizine in humans are unknown.

#### **Elimination**

Meclizine has a plasma elimination half-life of about 5-6 hours in humans.

#### Metabolism

In an *in vitro* metabolic study using human hepatic microsome and recombinant CYP enzyme, CYP2D6 was found to be the dominant enzyme for metabolism of meclizine.

# **13 NONCLINICAL TOXICOLOGY**

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

<u>Carcinogenesis</u>

Animal studies to assess the carcinogenic potential of meclizine have not been conducted.

<u>Mutagenesis</u>

Genetic toxicology studies of meclizine have not been conducted.

Impairment of Fertility

Animal studies to assess the effects of meclizine on fertility and early embryonic development have not been conducted.

# **16 HOW SUPPLIED/STORAGE AND HANDLING**

### 16.1 How Supplied

<u>Tablets</u>

Antivert<sup>®</sup> **12.5 mg** tablets are oval shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "34" and one white to off white layer debossed with "L". Bottles of 100 NDC 70199-002-01 Bottles of 500 NDC 70199-002-05 Antivert<sup>®</sup> **25 mg** tablets are oval shaped, biconvex, two-layered tablet, one yellow to pale yellow layer debossed with "49" and one white to off white layer debossed with "L". Bottles of 100 NDC 70199-003-01 Bottles of 1000 NDC 70199-003-99 Antivert<sup>®</sup> **50 mg** tablets are oval shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "50" and one yellow to pale yellow layer and debossed with "L". Bottles of 100 NDC 70199-004-01 Bottles of 1000 NDC 70199-004-99

Chewable Tablets

Antivert<sup>®</sup> **25 mg** chewable tablets are pink colored round tablets debossed with "M 25" on one side and break line on other side.

Bottles of 100

NDC 70199-018-01

# 16.2 Storage and Handling

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container (USP).

# **17 PATIENT COUNSELING INFORMATION**

#### Administration Instructions

Advise patients that the tablets must be swallowed whole, but chewable tablets must be chewed or crushed completely before swallowing [*see Dosage and Administration (2.1)*].

### Adverse Reactions

Advise patients that ANTIVERT<sup>®</sup> may cause anaphylactic reaction, drowsiness, dry

mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision [see Warnings and Precautions (5.1), Adverse Reactions (6)].

Inform patients that ANTIVERT<sup>®</sup> may impair their ability to engage in potentially dangerous activities, such as operating machinery or vehicles.

#### Concomitant Drug Interactions

Advise patients regarding medications that should not be taken in combination with ANTIVERT<sup>®</sup> or that may necessitate increased monitoring [see Drug Interactions (7.1, 7.2)]. Inform patients that alcohol may increase adverse reactions.

#### **Concurrent Medical Conditions**

Advise patients to notify their healthcare provider about all of their medical conditions, including if they are pregnant or plan to become pregnant or if they are breastfeeding [see Warnings and Precautions (5.2), Use in Specific Populations (8.1, 8.2)].

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PIB00499-08

Manufactured for: **Casper Pharma LLC** East Brunswick, NJ 08816

**Revised: 07/2019** 

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

#### NDC 70199-002-01



NDC 70199-003-01

issued: 03/2019

Antivert<sup>®</sup> (meclizine HCI) 25 mg Tablets USP 25 mg **Rx Only Container Label** 

Each tablet contains: 25 mg medizine dihydrochloride equivalent to 21.07 mg of medizine free base.	Rx only NDC 70199-003-01	Manufactured for: Casper Pharma LLC Casper Barma LLC Casper Barma LLC Casper Brunswick, NJ 08816
USUAL DOSAGE: See accompanying prescribing Information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response.	Antivert® (meclizine HCI)	Made in India. 99 Code: TS/DRUGS/22/2009 00 LB00301-05 03
Dispense in tight, light – resistant containers (USP). Keep this and all medication out of the reach of children.	Tablets USP 25 mg	P1422607
Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].	Casper 100 Tablets	
Issued: 03/2019	Casper 100 Tablets	
NDC 70199-004-01		L

Antivert®(meclizine HCl) 50 mg Tablets USP 50 mg Rx Only Container Label					
Each tablet contains: 50 mg meclizine dihydrochloride equivalent to 42.14 mg of meclizine free base.	Rx only NDC 70199-004-01	1 Manufactured for: Casper Pharma LLC East Brunswick, NJ 08816	N 3 7 0		
USUAL DOSAGE: See accompanying prescribing Information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response.	Antivert® (meclizine HCI)	Made in India. Code: TS/DRUGS/22/2009 LB00401-05	19900401		
Dispense in tight, light – resistant containers (USP). Keep this and all medication out of the reach of children.	Tablets USP 50 mg	P1422609	N		

Casper

Antivert® (meclizine HCI) 25 mg Chewable Tablets USP

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Issued: 03/2019

# NDC 70199-018-01

. ® /

F	25 mg Rx Only Container Label					
	Each chewable tablet contains: 25 mg meclizine dihydrochloride equivalent to 21.07 mg of meclizine free base.	Rx only	NDC 70	0199- <b>018</b> -01	Manufactured for: Casper Pharma, LLC East Brunswick, NJ 08816	N 3 7 0
	Chew or crush tablets completely before swallowing. Do not swallow tablets whole. USUAL DOSAGE: See accompanying prescribing Information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response. Dispense in tight, light – resistant containers (USP).	(mec Chew		e HCI) ablets	Made in India Code: TS/DRUGS/22/2009 LB01801-01 P1420542	199018019
	Keep this and all medication out of the reach of children. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Issued: 06/2019	Caspe	er	100 Tablets		

100 Tablets

Product Info	rmation					
Product Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC:	70199-002
Route of Admin	istration	ORAL				
Route of Admin						
Active Ingred	ient/Active	Moiety				
	Ingre	dient Name		Basis of S	trength	Strengt
<b>MECLIZINE HYDR</b> UNII:3L5TQ84570)	-	III: HDP7W44CIO) (MECLIZINE -		MECLIZ INE HYDROCHLORIE		12.5 mg
Inactive Ingre	edients					
		Ingredient Name			9	Strength
STARCH, CORN (L	JNII: 08232NY3SJ	)				
SUCROSE (UNII: C	151H8M554)					
WATER (UNII: 0590	QF0KO0R)					
POLYETHYLENE O	GLYCOL, UNSPE	CIFIED (UNII: 3WJQ0SDW1A)				
	ARATE (UNII: 700	97M6I30)				
MAGNESIUM STE						
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 31	<b>L</b> (UNII: H3R47K3 <sup>-</sup> K9958V90M)	TBD)				
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 31	<b>L</b> (UNII: H3R47K3 <sup>-</sup> K9958V90M)					
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 31 ANHYDROUS DIBA	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F	TBD)				
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 31 ANHYDROUS DIBA Product Char	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F	TBD) PHOSPHATE (UNII: L11K75P92J)		Score	n	10 score
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 31 ANHYDROUS DIBA Product Char Color	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F ACTERISTICS BLUE (Pale Blue	TBD) PHOSPHATE (UNII: L11K75P92J) to White)		Score Size		io score .0mm
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F ACTERISTICS BLUE (Pale Blue	TBD) PHOSPHATE (UNII: L11K75P92J)		Size	1	.0mm
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F ACTERISTICS BLUE (Pale Blue	TBD) PHOSPHATE (UNII: L11K75P92J) to White)			1	
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F ACTERISTICS BLUE (Pale Blue	TBD) PHOSPHATE (UNII: L11K75P92J) to White)		Size	1	.0mm
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F ACTERISTICS BLUE (Pale Blue	TBD) PHOSPHATE (UNII: L11K75P92J) to White)		Size	1	.0mm
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F acteristics BLUE (Pale Blue OVAL (Biconvex,	TBD) PHOSPHATE (UNII: L11K75P92J) to White)	Marl	Size	1 3 Marke	.0mm
MAGNESIUM STEA FD&C BLUE NO. 3 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging # Item Code	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F acteristics BLUE (Pale Blue OVAL (Biconvex, Pac 100 in 1 BOTTH Product	TBD) PHOSPHATE (UNII: L11K75P92J) to White) two layered tablet) kage Description LE; Type 0: Not a Combination	<b>Marl</b> 01/15/2	Size Imprint Code keting Start Date	1 3 Marke	.0mm 94;L eting End
MAGNESIUM STEA FD&C BLUE NO. 1 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-002- 01	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F acteristics BLUE (Pale Blue OVAL (Biconvex, Pac 100 in 1 BOTTH Product	TBD) PHOSPHATE (UNII: L11K75P92J) to White) two layered tablet) kage Description		Size Imprint Code keting Start Date	1 3 Marke	.0mm 94;L eting End
MAGNESIUM STEA FD&C BLUE NO. 12 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-002- 01 2 NDC:70199-002-	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F CALCIUM F BLUE (Pale Blue OVAL (Biconvex, VAL (Biconvex, Pac 100 in 1 BOTTI Product 500 in 1 BOTTI	TBD) PHOSPHATE (UNII: L11K75P92J) to White) two layered tablet) kage Description LE; Type 0: Not a Combination	01/15/2	Size Imprint Code keting Start Date	1 3 Marke	.0mm 94;L eting End
MAGNESIUM STEA FD&C BLUE NO. 12 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-002- 01 2 NDC:70199-002- 05	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM F BLUE (Pale Blue OVAL (Biconvex, Pac 100 in 1 BOTTI Product 500 in 1 BOTTI Product	TBD) PHOSPHATE (UNII: L11K75P92J) to White) two layered tablet)  kage Description E; Type 0: Not a Combination E; Type 0: Not a Combination	01/15/2	Size Imprint Code keting Start Date	1 3 Marke	.0mm 94;L eting End
MAGNESIUM STEA FD&C BLUE NO. 12 ALCOHOL (UNII: 3) ANHYDROUS DIBA Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-002- 01 2 NDC:70199-002-	L (UNII: H3R47K3 K9958V90M) ASIC CALCIUM I CALCIUM I BLUE (Pale Blue OVAL (Biconvex, Pac Pac 100 in 1 BOTTI Product 500 in 1 BOTTI Product Informati	TBD) PHOSPHATE (UNII: L11K75P92J) to White) two layered tablet)  kage Description E; Type 0: Not a Combination E; Type 0: Not a Combination	01/15/2	Size Imprint Code keting Start Date	1 Marke Mark	.0mm 94;L eting End

meclizine hcl tak						
Product Info	rmation					
Product Type		HUMAN PRESCRIPTION DRUG	Item 0	Code (Source)	NDC:	70199-003
Route of Admin	istration	ORAL				
Active Ingred	ient/Active	Moiety				
	Ingre	dient Name		Basis of S	trength	Strengt
<b>MECLIZINE HYDR</b> UNII:3L5TQ84570)	OCHLORIDE (UN	III: HDP7W44CIO) (MECLIZINE -		MECLIZ INE HYDROCHLORIE	DE	25 mg
Inactive Ingro	edients					
		Ingredient Name			2	Strength
ANHYDROUS DIB	ASIC CALCIUM	PHOSPHATE (UNII: L11K75P92J)				
STARCH, CORN (U	JNII: 08232NY3SJ	)				
SUCROSE (UNII: C	151H8M554)					
<b>WATER</b> (UNII: 0590						
		CIFIED (UNII: 3WJQ0SDW1A)				
POLYETHYLENE ( MAGNESIUM STE	GLYCOL, UNSPE ARATE (UNII: 700	)97M6I30)				
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77VI	097M6I30) EI93A8)				
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77VI	097M6I30) EI93A8)				
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77VI	097M6I30) EI93A8)				
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77VI . 10 (UNII: 355W	097M6I30) EI93A8)				
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b>	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77VI . 10 (UNII: 355W	097M6I30) EI93A8) 5USQ3G)		Score	r	10 score
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b> Color	GLYCOL, UNSPE ARATE (UNII: 700 0.6 (UNII: H777 .10 (UNII: 355W acteristics YELLOW (Pale Ye	097M6I30) EI93A8) 5USQ3G)		Score Size		io score .3mm
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b> Color Shape	GLYCOL, UNSPE ARATE (UNII: 700 0.6 (UNII: H777 .10 (UNII: 355W acteristics YELLOW (Pale Ye	297M6I30) EI93A8) 5USQ3G) ellow to White)	9		1	
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b> Color Shape Flavor	GLYCOL, UNSPE ARATE (UNII: 700 0.6 (UNII: H777 .10 (UNII: 355W acteristics YELLOW (Pale Ye	297M6I30) EI93A8) 5USQ3G) ellow to White)	9	Size	1	.3mm
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b> Color Shape Flavor	GLYCOL, UNSPE ARATE (UNII: 700 0.6 (UNII: H777 .10 (UNII: 355W acteristics YELLOW (Pale Ye	297M6I30) EI93A8) 5USQ3G) ellow to White)	9	Size	1	.3mm
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO <b>Product Char</b> Color Shape Flavor Contains	GLYCOL, UNSPE ARATE (UNII: 700 0.6 (UNII: H777 .10 (UNII: 355W acteristics YELLOW (Pale Ye	297M6I30) EI93A8) 5USQ3G) ellow to White)	9	Size	1	.3mm
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77V . 10 (UNII: 355W Acteristics YELLOW (Pale Ye OVAL (Biconvex,	297M6I30) EI93A8) 5USQ3G) ellow to White)	1	Size	1 4 Marke	.3mm
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging # Item Code	GLYCOL, UNSPE ARATE (UNII: 700 O. 6 (UNII: H77V . 10 (UNII: 355W Acteristics YELLOW (Pale Ye OVAL (Biconvex, Pac	097M6I30) EI93A8) 5USQ3G) ellow to White) two layered tablet)	1	Size mprint Code ceting Start Date	1 4 Marke	.3mm 19;L eting End
POLYETHYLENE ( MAGNESIUM STEA FD&C YELLOW N D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-003 01	ARATE (UNII: 700 O. 6 (UNII: H77VI . 10 (UNII: 355W) acteristics YELLOW (Pale Ye OVAL (Biconvex, Pac Pac 100 in 1 BOTTI Product	297M6I30) EI93A8) 5USQ3G) ellow to White) two layered tablet) <b>two layered tablet</b>	Mark	Size mprint Code seting Start Date	1 4 Marke	.3mm 19;L eting End
POLYETHYLENE ( MAGNESIUM STE FD&C YELLOW N D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-003 01 2 NDC:70199-003	ARATE (UNII: 700 O. 6 (UNII: H77VI . 10 (UNII: 355W) acteristics YELLOW (Pale Ye OVAL (Biconvex, VAL (Biconvex, 100 in 1 BOTTI Product . 1000 in 1 BOTTI	297M6I30) EI93A8) 5USQ3G) ellow to White) two layered tablet) two layered tablet Ekage Description	Mark 01/15/20	Size mprint Code seting Start Date	1 4 Marke	.3mm 19;L eting End
POLYETHYLENE ( MAGNESIUM STEA FD&C YELLOW N D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-003 01 2 NDC:70199-003	ARATE (UNII: 700 O. 6 (UNII: H7777 . 10 (UNII: 355W acteristics YELLOW (Pale Ye OVAL (Biconvex, Pac Pac 100 in 1 BOTTI Product 1000 in 1 BOTTI Product	297M6I30) EI93A8) 5USQ3G) ellow to White) two layered tablet) two layered tablet) E <b>: Kage Description</b> E; Type 0: Not a Combination TLE; Type 0: Not a Combination	Mark 01/15/20	Size mprint Code seting Start Date	1 4 Marke	.3mm 19;L eting End
MAGNESIUM STEA FD&C YELLOW NO D&C YELLOW NO Product Char Color Shape Flavor Contains Packaging # Item Code 1 NDC:70199-003 01	ARATE (UNII: 700 O. 6 (UNII: H77V) . 10 (UNII: 355W) ACTERISTICS YELLOW (Pale Ye OVAL (Biconvex, Pac Pac 100 in 1 BOTTI Product 1000 in 1 BOTTI Product	297M6I30) EI93A8) 5USQ3G) ellow to White) two layered tablet) two layered tablet) E <b>: Kage Description</b> E; Type 0: Not a Combination TLE; Type 0: Not a Combination	Mark 01/15/20	Size mprint Code seting Start Date	1 Marke	.3mm 19;L eting End

	<b>ITIVERT</b> clizine hcl tab	let				
Pr	oduct Infor	mation				
Pr	oduct Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:7	0199-004
	ute of Admini	stration	ORAL			
NU						
Ac	tive Ingredi	ent/Active	Moiety			
		Ingre	dient Name	Basis of S	Strength	Strengt
	CLIZINE HYDRO I:3L5TQ84570)	OCHLORIDE (UI	NII: HDP7W44CIO) (MECLIZINE -	MECLIZ INE HYDROCHLORI	DE	50 mg
In	active Ingre	dients				
			Ingredient Name		S	trength
	HYDROUS DIBA &C YELLOW NO		PHOSPHATE (UNII: L11K75P92J) EI93A8)			
D&	C YELLOW NO.	<b>10</b> (UNII: 355W	/5USQ3G)			
	ARCH, CORN (U		])			
	CROSE (UNII: C1					
	<b>TER</b> (UNII: 059Q					
	GNESIUM STEA		CIFIED (UNII: 3WJQ0SDW1A)			
	&C BLUE NO. 1	-	· ·			
	COHOL (UNII: 3K					
Pr	oduct Chara	acteristics				
Co	lor	BLUE (Pale Blue	to Yellow)	Score	2	pieces
Sh	ape	OVAL (Biconvex,	two layered tablet)	Size	1	6mm
Fla	vor			Imprint Code	5	0;L
Co	ntains					
Pa	ckaging					
#	Item Code	Pa	ckage Description	Marketing Start Date		ting End ate
-	01	Product	LE; Type 0: Not a Combination	01/15/2020		
	NDC:70199-004- 99	1000 in 1 BOT Product	TLE; Type 0: Not a Combination	01/15/2020		
	arketing	Informat	ion			
Μ	<b>–</b>			Marketing Start	Marke	ting End
M	Marketing Category	Applica	tion Number or Monograph Citation	Date		ate

ANTIVERT						
meclizine hcl tabl	et, chewable	<b>!</b>				
Product Infor	mation					
Product Type		HUMAN PRESCRIPTION DRUG	ltem C	ode (Source)	NDC:7	0199-018
Route of Administration ORAL ORAL						
Noute of Autom	Strution					
Active Ingredi	ent/Active	Moiety				
	Ingre	dient Name		Basis of S	trength	Strength
	CHLORIDE (UI	NII: HDP7W44CIO) (MECLIZINE -		MECLIZ INE		25 mg
UNII:3L5TQ84570)				HYDROCHLORIE	DE	_0g
Inactive Ingre	dients					
g. e		Ingredient Name			Stre	ength
STARCH, CORN (UN	NII: 08232NY3S	-				
SILICON DIOXIDE (	UNII: ETJ7Z6XB	U4)				
FD&C RED NO. 40	(UNII: WZ B912	7XOA)				
LACTOSE MONOH	<b>YDRATE</b> (UNII:	EWQ57Q8I5X)				
MAGNESIUM STEA	RATE (UNII: 70	097M6I30)				
RASPBERRY (UNII: 4	4N14V5R27W)					
SACCHARIN SODIU		JX40TY)				
TALC (UNII: 7SEV7J4	R1U)					
Product Chara	cteristics					
Color	PINK		Score		2 pie	eces
Shape	ROUND (Rou	ind tablets)	Size		8mm	
Flavor	RASPBERRY		Imprint	Code	M;25	<b>b</b>
Contains						
Packaging						
# Item Code	Pac	kage Description		eting Start Date		ting End ate
<b>1</b> NDC:70199-018- 01	100 in 1 BOTT Product	LE; Type 0: Not a Combination	01/15/202	20		
Marketing I	nformat	ion				
Marketing Category		tion Number or Monograph Citation	Mar	keting Start Date		ting End Date
NDA	NDA010721		01/15/2	2020		

# Labeler - Casper Pharma LLC (080025838)

Establishment					
Name	Address	ID/FEI	Business Operations		
Aurobindo Pharma Limited		650381903	ANALYSIS(70199-002, 70199-003, 70199-004, 70199-018), MANUFACTURE(70199-002, 70199-003, 70199-004, 70199-018)		

Revised: 10/2022

Casper Pharma LLC