

**DOXEPIN HYDROCHLORIDE- doxepin hydrochloride capsule**  
**Zydus Lifesciences Limited**

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**DOXEPIN HYDROCHLORIDE CAPSULES, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1385-1

Doxepin Hydrochloride Capsules USP, 10 mg

Rx only

100 Capsules

3  
725781139018  
8

GUJDRUGS/G/25/1486  
Rev.: 07/24

**Doxepin  
Hydrochloride  
Capsules, USP**

**10 mg\***

PHARMACIST: Dispense the Medication  
Guide provided separately to each patient.

VIONA

**100 Capsules**  
Rx only

\*Each hard gelatin capsule contains  
Doxepin hydrochloride, USP equivalent  
to Doxepin 10 mg.  
**Usual Dosage:** See accompanying  
Prescribing Information.  
**This package is child resistant.**  
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).  
**Keep this and all drugs out of the  
reach of children.**  
Product of Italy  
Medication Guide available at [www.vionausa.com/  
medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Mfg. by: Zydus Lifesciences Ltd.,  
Ahmedabad, India**

NDC 70771-1386-1

Doxepin Hydrochloride Capsules USP, 25 mg

Rx only

100 Capsules

3 N  
7 2 5 7 8 1 4 0 0 1  
4

GUJDRUGS/G/25/1486  
Rev.: 07/24

# Doxepin Hydrochloride Capsules, USP

## 25 mg\*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules Rx only

\*Each hard gelatin capsule contains Doxepin hydrochloride, USP equivalent to Doxepin 25 mg.  
**Usual Dosage:** See accompanying Prescribing Information.  
**This package is child resistant.**  
 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).  
**Keep this and all drugs out of the reach of children.**  
 Product of Italy  
 Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India**

NDC 70771-1387-1

Doxepin Hydrochloride Capsules USP, 50 mg

Rx only

100 Capsules

3 N  
7 2 5 7 8 1 4 1 0 1  
1

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Rev.: 07/24

# Doxepin Hydrochloride Capsules, USP

## 50 mg\*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules Rx only

\*Each hard gelatin capsule contains Doxepin hydrochloride, USP equivalent to Doxepin 50 mg.  
**Usual Dosage:** See accompanying Prescribing Information.  
**This package is child resistant.**  
 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).  
**Keep this and all drugs out of the reach of children.**  
 Product of Italy  
 Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India**

NDC 70771-1388-1

Doxepin Hydrochloride Capsules USP, 75 mg

Rx only

100 Capsules

3 725781142011 8

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# Doxepin Hydrochloride Capsules, USP

## 75 mg\*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules Rx only

\*Each hard gelatin capsule contains Doxepin hydrochloride, USP equivalent to Doxepin 75 mg.  
**Usual Dosage:** See accompanying Prescribing Information.  
**This package is child resistant.**  
 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).  
**Keep this and all drugs out of the reach of children.**  
 Product of Italy  
 Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India**

NDC 70771-1389-1

Doxepin Hydrochloride Capsules USP, 100 mg

Rx only

100 Capsules

3 725781143011 5

GUJDRUGS/G/25/1486

Rev.: 07/24

# Doxepin Hydrochloride Capsules, USP

## 100 mg\*

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules Rx only

\*Each hard gelatin capsule contains Doxepin hydrochloride, USP equivalent to Doxepin 100 mg.  
**Usual Dosage:** See accompanying Prescribing Information.  
**This package is child resistant.**  
 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).  
**Keep this and all drugs out of the reach of children.**  
 Product of Italy  
 Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
**Mfg. by: Zydus Lifesciences Ltd., Ahmedabad, India**

## DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1385
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOXEPIN HYDROCHLORIDE</b> (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	WHITE (opaque white cap) , WHITE (opaque white body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	1296
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1385-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1385-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
3	NDC:70771-1385-4	10 in 1 CARTON	03/01/2024	
3	NDC:70771-1385-2	10 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
ANDA	ANDA210700	03/01/2024	

## DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1386
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	25 mg

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	YELLOW (opaque yellow cap) , WHITE (opaque white body)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	1297
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1386-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1386-4	10 in 1 CARTON	03/01/2024	
2	NDC:70771-1386-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70771-1386-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210700	03/01/2024	

## DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1387
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	50 mg

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	YELLOW (opaque yellow cap) , YELLOW (opaque yellow body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	1298
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1387-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1387-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
3	NDC:70771-1387-4	10 in 1 CARTON	03/01/2024	
3	NDC:70771-1387-2	10 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
ANDA	ANDA210700	03/01/2024	

## DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1388
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOXEPIN HYDROCHLORIDE</b> (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	75 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	GREEN (opaque green cap) , GREEN (opaque green body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	1299
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1388-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1388-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
3	NDC:70771-1388-4	10 in 1 CARTON	03/01/2024	
3	NDC:70771-1388-2	10 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
ANDA	ANDA210700	03/01/2024	

## DOXEPIN HYDROCHLORIDE

doxepin hydrochloride capsule



**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1389
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOXEPIN HYDROCHLORIDE</b> (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	100 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	GREEN (opaque green cap) , WHITE (opaque white body)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	1300
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1389-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:70771-1389-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
3	NDC:70771-1389-4	10 in 1 CARTON	03/01/2024	
3	NDC:70771-1389-2	10 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
ANDA	ANDA210700	03/01/2024	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1385, 70771-1386, 70771-1387, 70771-1388, 70771-1389) , MANUFACTURE(70771-1385, 70771-1386, 70771-1387, 70771-1388, 70771-1389)

Revised: 7/2024

Zydus Lifesciences Limited