

**DOXEPIN- doxepin tablet**  
**Zydus Lifesciences Limited**

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**DOXEPIN tablets, for oral use**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1528-3 in bottle of 30 tablets

Doxepin Tablets, 3 mg

Rx only

30 tablets

XXXXXXXX  
Rev.: 06/24

**Doxepin Tablets**

**3 mg**

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

**30 Tablets**  
**Rx only**

VIONA

Each tablet contains 3.39 mg Doxepin Hydrochloride, USP equivalent to 3 mg of Doxepin.  
**Usual Dosage:** See package insert for complete prescribing information.  
**This package is child-resistant.**  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]. Protect from light. Dispense in a tight, light resistant container.  
**Keep this and all drugs out of the reach of children.**  
Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
Mfd. by: Zydus Lifesciences Ltd., Ahmedabad, India

NDC 70771-1529-3 in bottle of 30 tablets

Doxepin Tablets, 6 mg

Rx only

30 tablets

XXXXXXXX  
Rev.: 06/24

**Doxepin Tablets**

**6 mg**

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

**30 Tablets**  
**Rx only**

VIONA

Each tablet contains 6.78 mg Doxepin Hydrochloride, USP equivalent to 6 mg of Doxepin.  
**Usual Dosage:** See package insert for complete prescribing information.  
**This package is child-resistant.**  
Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]. Protect from light. Dispense in a tight, light resistant container.  
**Keep this and all drugs out of the reach of children.**  
Medication Guide available at [www.vionausa.com/medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.  
Mfd. by: Zydus Lifesciences Ltd., Ahmedabad, India

**DOXEPIN**

doxepin tablet

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1528
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	BLUE (LIGHT BLUE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	393
<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:70771-1528-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
2	NDC:70771-1528-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
3	NDC:70771-1528-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
4	NDC:70771-1528-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
5	NDC:70771-1528-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
6	NDC:70771-1528-4	10 in 1 CARTON	06/30/2024	
6		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	ANDA202761	06/30/2024	

## DOXEPIN

doxepin tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1529
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXEPIN HYDROCHLORIDE (UNII: 3U9A0FE9N5) (DOXEPIN - UNII:5ASJ6HUZ7D)	DOXEPIN	6 mg

### Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	GREEN (LIGHT GREEN)	Score	no score
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	394
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1529-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
2	NDC:70771-1529-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
3	NDC:70771-1529-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
4	NDC:70771-1529-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
5	NDC:70771-1529-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2024	
	NDC:70771-			

6	NDC: 70771-1529-4	10 in 1 CARTON	06/30/2024	
6		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	ANDA202761		06/30/2024	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1528, 70771-1529) , MANUFACTURE(70771-1528, 70771-1529)

Revised: 6/2024

Zydus Lifesciences Limited