

**DAPSONE- dapsona gel**  
**Zydus Lifesciences Limited**

**Dapsona Gel**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Dapsona Gel, 7.5%

60 g

NDC 70771-1538-3

Zydus

Rx only

The image shows a rectangular product label for Dapsona Gel. The label has a white background with magenta and blue accents. On the left side, there is a large magenta graphic element. The text on the label includes the product name 'Dapsona Gel' in large black font, followed by '7.5%' in white text on a magenta background. Below this, it says 'FOR TOPICAL USE ONLY'. At the bottom left, there is the VIONA logo and '60 g Rx only'. On the right side, there is a block of text providing usage instructions, dosage, warnings, and ingredients. A barcode is located on the right side, with the number '3 72578 09402 7' printed below it. At the bottom right, there is a dashed box with a blue arrow pointing to it, and the text 'Rev.: 05/24 XXXXXXX'.

**Dapsona**  
**Gel**

**7.5%**

FOR TOPICAL USE ONLY

**FOR TOPICAL USE ONLY:** Not for oral, ophthalmic, or intravaginal use.  
**Usual dosage:** Apply once daily. See package insert for complete prescribing information.  
**WARNING:** Keep this and all drugs out of the reach of children.  
Each gram of gel contains 75 mg of dapsona USP.  
**Inactive ingredients:** diethylene glycol monoethyl ether, methylparaben, acrylamide/sodium acryloyldimethyl taurate copolymer, isohexadecane, polysorbate 80 and purified water.  
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. **Protect from freezing.**

**Manufactured by: Zydus Lifesciences Ltd.**  
Ahmedabad, India

Rev.: 05/24  
XXXXXXX

60 g  
Rx only

VIONA

3 72578 09402 7



  
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 60 g  
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**Dapsone Gel**  
**7.5%**

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xxxxxxx

**Dapsone Gel**  
**7.5%**  
 FOR TOPICAL USE ONLY  
  
 60 g  
 Rx only

Rev.: 05/24

**Manufactured by:**  
**Zydus Lifesciences Ltd.**  
 Ahmedabad, India  
  
 N 317257810940217

**Dapsone Gel**  
**7.5%**  
 FOR TOPICAL USE ONLY  
  
 60 g  
 Rx only

↑

dapsone gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1538
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)	DAPSONE	75 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
ACRYLAMIDE (UNII: 20R035KLCI)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	WHITE (off white to yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1538-2	1 in 1 CARTON	05/10/2024	
1		30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:70771-1538-3	1 in 1 CARTON	05/10/2024	
2		60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:70771-1538-8	1 in 1 CARTON	05/10/2024	
3		90 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

**Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA214019	05/10/2024	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		650650802	ANALYSIS(70771-1538) , MANUFACTURE(70771-1538)

Revised: 5/2024

Zydus Lifesciences Limited