

**ASPIRIN- aspirin tablet, film coated**  
**HIMPRIT PHARMACHEM PVT LTD**

*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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**ASPIRIN 325 MG TABLETS**

***Drug Facts***

**Active ingredient (in each tablet)**

Aspirin 325 mg

**Purposes**

Pain reliever/fever reducer

**Uses**

temporarily relieves

- headache
- muscle pain
- toothache
- menstrual pain
- pain and fever of colds
- minor pain of arthritis

**Warnings**

**Reye's syndrome**

Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

**Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Alcohol warning**

If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

**Do not use** if you are allergic to aspirin or any other pain reliever/fever reducer.

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

- stomach problems (such as heartburn, upset stomach, or stomach pain) that last or come back
- bleeding problems
- ulcers

- asthma

**Ask a doctor or pharmacist before use if you are** taking a prescription drug for

- anticoagulation (blood thinning)
- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever lasts more than 3 days
- new symptoms occur
- ringing in the ears or loss of hearing occurs

**If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 or 2 tablets every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
- children under 12 years: consult a doctor

**Other information**

- save carton for full directions and warnings
- store at room temperature

**Inactive ingredients**

carnauba wax<sup>1</sup>, corn starch, hypromellose, powdered cellulose, triacetin

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<sup>1</sup> may contain this ingredient

**PRINCIPAL DISPLAY PANEL**

**ASPIRIN 325 MG TABLETS**  
**Each Film coated Tablet Contains:**  
**ASPIRIN 325 MG**

Lot No :

MFG. DATE :

Exp. Date :

Jar No. :

Quantity : 50,000 Tablets

NDC. No : 65437-038-05

**WARNING :**

**KEEP OUT OF THE REACH OF CHILDREN**

STORE CONTROLLED ROOM TEMPERATURE OF 59° –86°F (15° – 30°C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT

CONFORMANCE WITH THE FDA AND REGULATIONS THEREUNDER

**MANUFACTURED BY:**

MANUFACTURED CODE No Guj/Drugs/G/1362

LABELER CODE # 14803

**MANUFACTURED FOR:**

**HIMPRIT PHARMACHEM PVT. LTD**

"LAKULISH", R.V.DESAI ROAD,

NEXT TO NAVAPURA POLICE STATION

BARODA, INDIA – 390 001

**CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"**

<b><u>ASPIRIN 325 MG TABLETS</u></b>			
<b><u>Each Film coated Tablet Contains:</u></b>			
ASPIRIN 325 MG			
Lot No	:	Jar No.	:
MFG. DATE	:	Quantity	: 50,000 Tablets
Exp. Date	:	NDC. No	: 65437-038-05
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LABELER CODE # 14803		"LAKULISH", R.V.DESAI ROAD,	
		NEXT TO NAVAPURA POLICE STATION	
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**ASPIRIN**

aspirin tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65437-038
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

**Inactive Ingredients**

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

Color	WHITE	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-038-05	1 in 1 DRUM		
1		50000 in 1 BAG		
2	NDC:65437-038-07	1 in 1 DRUM		
2		75000 in 1 BAG		
3	NDC:65437-038-10	1 in 1 DRUM		
3		100000 in 1 BAG		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/01/2010	

**Labeler** - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 2/2010

HIMPRIT PHARMACHEM PVT LTD