

ACETAMINOPHEN (RED)- acetaminophen (red) - acetaminophen capsule liquid filled capsule, liquid filled

One2zee Limited Liability Company

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.

ACETAMINOPHEN

Drug Facts

Active ingredient (in each capsule)

Acetaminophen 325 mg

Purpose

Pain reliever/ fever reducer

Uses

- Temporarily relieves minor aches and pains due to :
 - headache
 - muscular aches
 - backache
 - minor pain of arthritis
 - the common cold
 - toothache
 - premenstrual and menstrual cramps
- Temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if the user has liver disease

Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days in adults

- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Do not take more than directed
(see Overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"> • take 2 softgels every 4 to 6 hours while symptoms last • do not take more than 10 softgels in 24 hours • do not use for more than 10 days unless directed by a doctor
children 6-11 years	<ul style="list-style-type: none"> • take 1 softgel every 4 to 6 hours while symptoms last • do not take more than 5 softgels in 24 hours • do not use for more than 5 days unless directed by a doctor
children under 6 years	ask a doctor

Other Information

store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat

Inactive ingredients

FD&C red #40, gelatin, sorbitol, glycerin, polyethylene glycol 400, povidone K-30, propylene glycol, titanium dioxide, purified water

PRINCIPAL DISPLAY PANEL - Shipping Label

ACETAMINOPHEN CAPSULES, 325 mg

Quantity : 48 Bags of 300 Capsules each
NDC. No : 55629-718-01

Important:

1. Inspect immediately upon receipt
2. This is bulk shipment intended for further processing only
3. Store at controlled temperature of 59°F to 86°F (15°C to 30°C) avoid high humidity and excessive heat above 104°F (40°C)

Manufactured by: MEDGEL PRIVATE LIMITED Plot No. 19-20, Special Economic Zone-II (Pharma Zone), Sector-III, Pithampur, Distt. Dhar-454775, Madhya Pradesh, India	
NDC No: 55629-718-01	
Product: <p style="text-align: center;">Acetaminophen 325 mg Soft Gelatin Capsules</p> <p style="text-align: center;">Each softgel contains: Acetaminophen 325 mg</p> <p style="text-align: center;">Caution: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKGING</p>	
Product Code: <p style="text-align: center;">27-10001</p>	Package Size: <p style="text-align: center;">48 x 300 softgels</p>
Lot Number: <p style="text-align: center;">000000</p>	Manufacturing Date: 00/0000 Expiry Date: 00/0000
Shipper No. <p style="text-align: center;">0 of 00</p>	Important: 1. Inspect immediately upon receipt 2. This is bulk shipment intended for further processing only 3. Store at controlled temperature of 59°F to 86°F (15°C to 30°C) avoid high humidity and excessive heat above 104°F (40°C)
MADE IN INDIA	

ACETAMINOPHEN (RED)

acetaminophen (red) - acetaminophen capsule liquid filled capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55629-718
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K30 (UNII: U725QWY32X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	red	Score	no score
Shape	capsule (Oblong)	Size	20mm
Flavor		Imprint Code	718
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-718-01	48 in 1 BOX	02/25/2019	
1	NDC:55629-718-02	300 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/25/2019	

Labeler - One2zee Limited Liability Company (078656111)

Registrant - One2zee Limited Liability Company (078656111)

Establishment			
Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(55629-718) , analysis(55629-718)