

FORTOLIN- acetaminophen tablet
FORTUNE PHARMACAL COMPANY, LIMITED

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.

Drug Facts

Active ingredients
Acetaminophen 500 mg

Purpose
Pain reliever-fever reducer

Uses
For the temporary relief of minor aches and pains associated with the common cold
headache
toothache
muscular aches
To reduce fever

Warnings Alcohol warning:
If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.
Acetaminophen may cause liver damage

Do not use
on children under 3 years of age

Stop use and ask a doctor if
you need to use this product for pain for more than 10 days
fever lasts for more than 3 days (72 hours) or gets worse
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. In case of overdose, get medical help or contact a Poison Control Center right away.
Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms.

Directions
Take 1 tablet every 3 to 4 hours or 2 tablets every 6 hours while symptoms persist, not to exceed 8 tablets in 24 hours, or as directed by a doctor.
Children under 12 years of age : consult a doctor

Other information

Each tablet contains sodium 0.496 mg

Keep tightly closed

Store in original packaging, away from sunlight

Inactive ingredients

colloidal silicon dioxide, corn starch, lactose, magnesium stearate, povidone, sodium starch glycolate

Questions or comments?

(888) 221-3496 M-F 9 am to 5 pm PST

Fortolin

Pain Reliever Fever Reducer

NDC 51467-127-24

Aspirin Free

Contain no aspirin and are unlikely to cause gastric irritation.

Acetaminophen 500 mg

24 Tablets

Safety Sealed

Do not use if individually sealed foil unit dose pouches are torn, broken, or shows the evidence of being opened.



FORTOLIN acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51467-127
Route of Administration	ORAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg	
Inactive Ingredients				
Ingredient Name		Strength		
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
LACTOSE (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONE (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	12mm	
Flavor		Imprint Code	F;O;R;T;O;L;I;N	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51467-127-24	24 in 1 PACKAGE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	03/01/2004		

Labeler - FORTUNE PHARMACAL COMPANY, LIMITED (686280561)

Establishment

Name	Address	ID/FEI	Business Operations
FORTUNE PHARMACAL COMPANY, LIMITED		686280561	manufacture(51467-127)

Revised: 6/2014

FORTUNE PHARMACAL COMPANY, LIMITED