APINOPHEN EXTRA STRENGTH- acetaminophen tablet
A P J Laboratories 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.

---

active ingredient

Acetaminophen 500 mg

purpose

Pain reliever/fever reducer

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.

uses

temporarily relieves minor aches and pains due to:

the common cold
headache
backache
minor pain of arthritis
toothache
muscular aches
premenstrual and menstrual cramps
temporarily reduces fever

warning

Liver warning:

This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg) in 24 hours. Severe liver damage may occur if you take

more than 4,000 mg of acetaminophen in 24 hours

with other drugs containing acetaminophen

3 or more alcoholic drinks every day while using this product

directions

do not take more than directed (see overdose warning)

adults and children 12 years and over: take 2 caplets every 6 hours while symptoms last
swallow whole – do not crush, chew, or dissolve
do not take more than 6 caplets in 24 hours, unless directed by a doctor
do not use for more than 10 days unless directed by a doctor

children under 12 years : ask a doctor

LACTOSE MONOHYDRATE

STARCH, CORN

GELATIN

METHYLPARABEN

PROPYLPARABEN

MAGNESIUM STEARATE

TALC

SODIUM STARCH GLYCOLATE TYPE A POTATO

SILICON DIOXIDE

Enter section text here

APINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46084-061
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	10 mg
STARCH, CORN (UNII: O8232NY3SJ)	17 mg
GELATIN (UNII: 2G86QN327L)	2 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	10 mg
PROPYLPARABEN (UNII: Z8IX2SC1OH)	1 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	10 mg
TALC (UNII: 7SEV7J4R1U)	10 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	20 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1 mg

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	13mm
Flavor		**Imprint Code**	500mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-061-25	500 in 1 BLISTER PACK		
2	NDC:46084-061-24	250 in 1 BLISTER PACK		
3	NDC:46084-061-23	120 in 1 BLISTER PACK		
4	NDC:46084-061-22	60 in 1 BLISTER PACK		
5	NDC:46084-061-11	2 in 1 BLISTER PACK		
6	NDC:46084-061-26	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-061)