

ACETAMINOPHEN- acetaminophen tablet
Apotheca, Inc

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 TABLET 325MG

DRUG FACTS:
ACTIVE INGREDIENT

Acetaminophen 325mg

USES

Temporarily relieves minor aches and pains due to

- the common cold
- headache
- backache
- minor pain of arthritis
- toothache
- muscular aches
- menstrual cramps

Temporarily reduces fever

KEEP OUT OF REACH OF CHILDREN

INDICATIONS & USAGE

do not take more than directed

adults and children 12 years and over

take 1 to 2 tablets every 4 to 6 hours as needed. Do not take more than 8 tablets in 24 hours.

children 6 to under 12 years

take 1 tablet every 4 to 6 hours as needed. Do not take more than 5 tablets in 24 hours

children under 6 years

consult a doctor. Do not use this adult regular strength product in children under 6 years of age, this will provide more than the recommended dose (overdose) acetaminophen and may cause liver damage.

Tamper Evident: do not use if imprinted safety seal under cap is broken or missing
Store between 20-25oC (68-77oF)
Use by expiration date on package
To report adverse drug events call 1-800-332-1088

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- Adult takes more than 12 tablets in 24 hours, which is the maximum daily amount
- Child takes more than 5 doses in 24 hours
- 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 you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- Pain gets worse or lasts more than 10 days in adults and children
- 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 sign of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In the case of accidental overdose, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION**Directions**

- do not take more than directed (see overdose warning).

Adults and children 12 years and over	Take 2 tablets every 4 to 6 while symptoms last. Do not take more than 12 tablets in 24 hours.
Children 6 to under 12 years	Take 1 tablet every 4 to 6 while symptoms last. Do not take more than 5 tablets in 24 hours.
Children under 6 years	Do not use adult regular strength products in children under 6 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Other information

- **Tamper Evident: do not use if imprinted safety seal under cap is broken or missing**
- store between 20-25°C (68-77°F)
- use by expiration date on package

INACTIVE INGREDIENTS

Povidone, pregelatinized starch, sodium starch glycolate, stearic acid

PRINCIPAL DISPLAY PANEL

NDC 12634-111-74

Acetaminophen

NON-ASPIRIN

Pain & Fever

Reliever

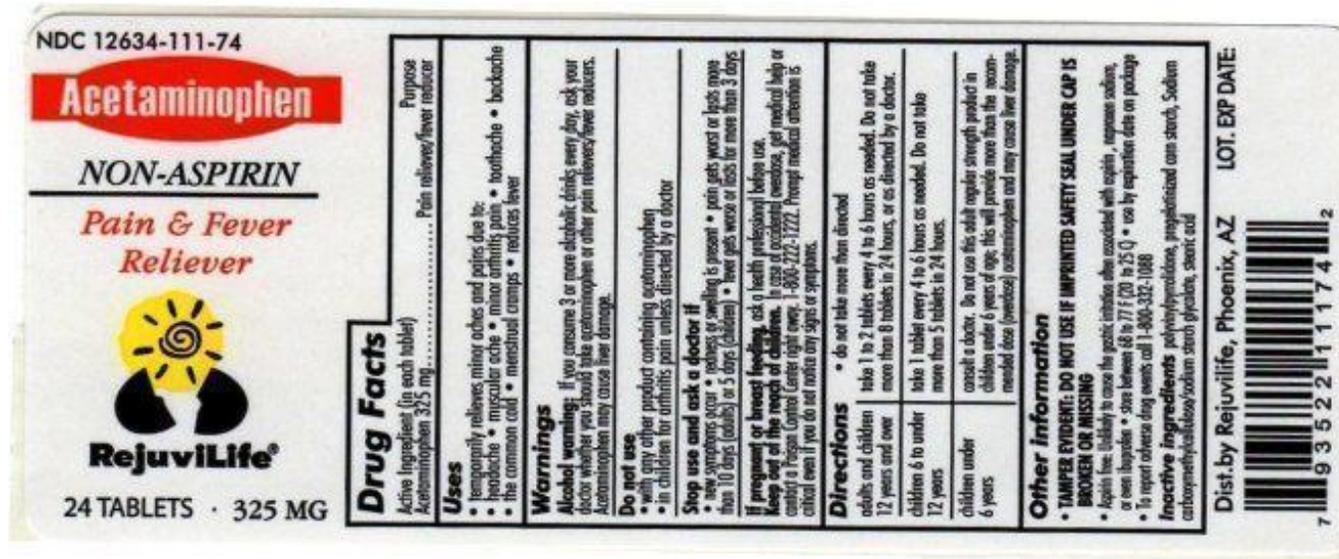
RejuviLife

24 TABLETS 325 MG

Distributed by:

RejuviLife, Phoenix, AZ

RejuviLife is a trademark of Apotheca, Inc



ACETAMINOPHEN			
acetaminophen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12634-111(NDC:16103-353)
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	

POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STARCH, POTATO (UNII: 8I089SAHBT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PH020
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-111-74	24 in 1 BOTTLE		
2	NDC:12634-111-60	60 in 1 BOTTLE		
3	NDC:12634-111-01	100 in 1 BOTTLE		
4	NDC:12634-111-10	1000 in 1 BOTTLE		
5	NDC:12634-111-91	1 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/1996	

Labeler - Apotheca, Inc (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca, Inc		051457844	relabel(12634-111)

Revised: 7/2013

Apotheca, Inc