

**CHEWABLE ACETAMINOPHEN CHILDRENS- acetaminophen tablet, chewable
Richmond Pharmaceuticals, 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.

APAP Children Chewable Tablets, 80 mg

Active ingredient (in each tablet)

Acetaminophen 80 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- sore throat
- flu
- toothache
- the common cold
- temporarily reduces fever

Warnings

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

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

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 your child is allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if your child has

liver disease.

Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- 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.

Keep out of reach of children.

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

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed**
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew before swallowing; this product will soften in mouth for ease of chewing
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	2
36-47	4-5	3
48-59	6-8	4
60-71	9-10	4-5
72-95	11-12	4-6

*or as directed by a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- **Phenylketonurics:each tablet contains: phenylalanine 5mg**

Inactive ingredients

aspartame, compressible sugar, D&C red #27(Al lake), dextrose, FD&C yellow #6(Al lake), fruit flavor, magnesium stearate, microcrystalline cellulose, prosweet, stearic acid

Questions or comments?

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR

MISSING

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

Principal display panel

NDC- 54738-092-30 - APAP 80MG CHEWABLE- 30 TABS

CHEWABLE ACETAMINOPHEN CHILDRENS

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54738-092
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
INVERT SUGAR (UNII: ED959S6ACY)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	pink (light)	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor	FRUIT	Imprint Code	AP;051
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54738-092-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/2015	

Labeler - Richmond Pharmaceuticals, Inc. (043569607)**Registrant** - Advance Pharmaceutical Inc. (078301063)**Establishment**

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(54738-092)

Revised: 10/2017

Richmond Pharmaceuticals, Inc.