

**ACETAMINOPHEN 80 MG FRUIT CHEW- acetaminophen tablet  
Proficient Rx LP**

*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.*

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**ACETAMINOPHEN USP 80 MG FRUIT CHEW TABLET**

***Drug Facts***

***Active ingredient (in each tablet)***

Acetaminophen USP, 80 mg

***Purposes***

Pain Reliever/Fever Reducer

***Uses***

temporarily reduces fever and relieves minor aches and pains caused by

- headache
- the common cold
- flu
- toothache
- sore throat

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if the 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, lasts for more than 2 days or 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 wheater a drug contains acetaminophen, ask a doctor or pharmacist.

**Ask a doctor before use if the child has** liver disease

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

***Drug Facts*** continued on back of label

## 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
- redness or swelling is present
- any new symptoms appear

These could be signs of a serious condition

## Keep out of reach of children.

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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 take more than directed (see Overdose warning)**
- find correct dose on chart below
- if possible, use weight to dose, otherwise use age
- chew tablets before swallowing
- give dose every 4 hours while symptoms last
- do not give more than 5 doses in 24 hours

Weight (pounds)	Age (years)	Dose (tablets)
72-95	11-12	4-6
60-71	9-10	4-5
48-59	6-8	4
36-47	4-5	3
24-35	2-3	2
under 24	under 2	ask a doctor

## Other information

- **Phenylketonurics : each tablet contains : phenylalanine 5 mg**

## Other information

- store at room temperature 15°-30°C (59°-86°F)

## Inactive ingredients

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

## Questions or comments?

call 516-341-0666 8:30 am - 4:30 pm ET, Monday - Friday

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

**BROKEN OR MISSING**

\*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Tylenol®.

Distributed by: **Reliable 1 Laboratories LLC, Valley Stream, NY 11580**

Repackaged by: Proficient Rx LP Thousand Oaks, CA 91320

Lot # 00000  
Exp. 00/00/00  
SN# MASTER

Acetaminophen 80mg  
#30 Chewable Tablets  
Lot # 00000 SN# MASTER  
NDC 63187-944-30 Exp. 00/00/00

Acetaminophen 80mg  
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Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

**NDC 63187-944-30**

**FRUIT FLAVORED**

**Acetaminophen USP 80 mg**

**PAIN RELIEVER**

**FEVER REDUCER**

**30 CHEWABLE TABLETS**

\*Compare to Active Ingredient in Children's TYLENOL®

<b>ACETAMINOPHEN 80 MG FRUIT CHEW</b>			
acetaminophen tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-944(NDC:69618-012)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

ASPARTAME (UNII: Z0H242BBR1)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
SUCROSE (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	pink (Light Pink)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;051
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-944-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	
2	NDC:63187-944-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	
3	NDC:63187-944-40	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	
4	NDC:63187-944-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	
5	NDC:63187-944-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2018	



# ACETAMINOPHEN 80mg Tablet

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/01/2015	

**Labeler** - Proficient Rx LP (079196022)

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079502574	REPACK(63187-944) , RELABEL(63187-944)

Revised: 12/2018

Proficient Rx LP