

**ACETAMINOPHEN - acetaminophen tablet, chewable**  
**Physicians Total Care, 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.*

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**Drug Facts**

**Active Ingredient (in each chewable tablet)**

Acetaminophen 80 mg

**Purposes**

Pain Reliever/Fever Reducer

**Uses**

Temporarily relieves minor aches and pain due to:

- The common cold ■ Flu ■ Headache ■ Sore throat
- Toothache

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.

**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 other drug containing acetaminophen (prescription or non prescription). 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 dose.**

**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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800- 222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

## Directions

- **This products does not contain directions or complete warnings for adult use.**
- Find right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- Chew before swallowing
- If needed, repeat dose every 4 hours while symptoms lasts
- Do not give more than 5 times in 24 hours
- Do not give for more than 5 days unless directed by a doctor.

Weight	Age	Tablets
Under 24 lbs	Under 2 years	Ask a doctor
24-35 lbs	2-3 years	2 tablets
36-47 lbs	4-5 years	3 tablets
48-59 lbs	6-8 years	4 tablets
60-71 lbs	9-10 years	5 tablets
72-95 lbs	11 years	6 tablets

## Other Information

- Phenylketonurics: Contain Phenylalanine 14 mg per tablet
- **Do not use if imprinted safety seal under cap is broken or missing**
- Store at room temperature in a dry place

## Inactive Ingredients

Aspartame, Colloidal Silica, D&C Red # 27 Lake, Hypromellose, Magnesium Stearate, Mannitol, Natural & Artificial Berry Flavors, Povidone, Pregelatinized Starch, Sodium Chloride, Sodium Starch Glycolate, Sorbitol, Stearic Acid and Sucralose.

## Questions?

Adverse Drug Event Call: (800) 616-2471

## Principal Display Panel



NDC 54868-5625-0

\*Compare to the active ingredient in Children's Chewable Tylenol®

Children's Chewable

AGES 2-6

**Acetaminophen** Chewable Tablets

30 Tablets, 80 mg EACH

**Fever reducer/ Pain reliever**

ASPIRIN FREE • IBUPROFEN FREE

**See New  
Warnings  
Information**

Fruit Flavor

## ACETAMINOPHEN

acetaminophen tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54868-5625(NDC:0904-5256)
<b>Route of Administration</b>	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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

**Product Characteristics**

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND BICONVEX TABLET)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	1G
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-5625-0	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	06/29/2006	

**Labeler** - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 6/2012

Physicians Total Care, Inc.