

PREMIER VALUE CHILDRENS ACETAMINOPHEN MELTS- acetaminophen tablet, chewable

Chain Drug Consortium

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.

Premier Value Children's Pain Reliever

Active ingredient (in each tablet)

Acetaminophen 80 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - flu
 - 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 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.

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 at 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.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see overdose warning)**
- find the right dose on chart. 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 years	ask a doctor
24-35	2-3 years	2 tablets
36-47	4-5 years	3 tablets
48-59	6-8 years	4 tablets
60-71	9-10 years years	5 tablets
72-95	11	6 tablets

Other information

- store at controlled room temperature 20-25°C (68-77°F). Avoid high humidity. Protect from light
- see end flap for expiration date and lot number

Inactive ingredients

citric acid, corn starch, crospovidone, D&C red 30 aluminum lake, dextrose, ethylcellulose, FD&C blue 1 aluminum lake, flavors, gelatin, maltodextrin, magnesium stearate, sucralose

Questions or comments?

1-866-467-2748

Product Packaging

NDC 68016-196-00

Compare to Children's Tylenol® Meltaways® Active Ingredient*

Premier Value

**Children's
Pain Reliever**

Ages 2-6

ACETAMINOPHEN

pain reliever/fever reducer
Aspirin Free/ Ibuprofen Free

GRAPE FLAVOR

30 count – 80mg each

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Children's Tylenol® Meltaways®.



Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	RP080
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-196-00	1 in 1 CARTON		
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/06/2004	

Labeler - Chain Drug Consortium (101668460)