

**GENEXA CHILDRENS ACETAMINOPHEN- acetaminophen tablet, chewable  
Genexa 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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**Children's Acetaminophen Chewable Tablets**

**Drug Facts**

**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
- sore throat
- flu
- toothache
- headache
- 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 dose (see Overdose warning)**

**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:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 (see Overdose warning)**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- chew tablets completely before swallowing; do not swallow tablets whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

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<b>Weight</b>	<b>Age</b>	<b>Dose †</b>
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

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†or as directed by a doctor

**Other information**

- each tablet contains: **calcium 10 mg**
- store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.

**Inactive ingredients**

acacia gum‡, calcium carbonate‡, organic carnauba wax, cellulose‡, citric acid‡, dextrose‡, dibehenin (vegetable source)‡, flavor‡, glycerin‡, grape flavor‡, organic guar gum, maltodextrin‡, organic palm olein, organic stevia rebaudiana leaf extract, organic sunflower lecithin, xylitol‡

‡ natural

**Questions? 1-855-436-3921**

**Carton and bottle are safety sealed. DO NOT use if seal on top and/or bottom of carton or under cap of bottle is disturbed or missing.**

\*This product is not manufactured or distributed by Johnson & Johnson Inc., owner of the registered trademark Children's Tylenol® Chewables Grape.

Patent Pending | Distributed by: Genexa Inc.

Atlanta, GA 30318 | genexa.com

Made in the USA with globally sourced ingredients

R-20211230

NDC 69676-0058-7

**Children's**

**Genexa®**

**MEDICINE MADE CLEAN**

**Ages 2-11**

**Acetaminophen Chewables**

**Pain Reliever Fever Reducer**

**How we're different**

**Made without:** crospovidone, D&C red no. 30 aluminum lake, sucralose **& more!**

**Read our label vs. Children's Tylenol® Chewables Grape\***

**24 Chewable Tablets**

**80 mg each**

**Grape Flavor**

<p><b>Drug Facts (continued)</b></p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist</li> <li>if your child is allergic to acetaminophen or any of the inactive ingredients in this product</li> </ul> <p><b>Ask a doctor before use if your child has liver disease</b></p> <p><b>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin</b></p> <p><b>When using this product do not exceed recommended dose (see Overdose warning)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>pain gets worse or lasts more than 5 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>new symptoms occur</li> <li>redness or swelling is present</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>this product does not contain directions or complete warnings for adult use.</li> <li>do not give more than directed (see Overdose warning)</li> <li>find right dose on chart below. If possible, use weight to dose; otherwise, use age.</li> <li>chew tablets completely before swallowing; do not swallow tablets whole</li> <li>repeat dose every 4 hours while symptoms last</li> <li>do not give more than 5 times in 24 hours</li> </ul> <table border="1"> <thead> <tr> <th>Weight</th> <th>Age</th> <th>Dose**</th> </tr> </thead> <tbody> <tr> <td>Under 24 lbs.</td> <td>Under 2 years</td> <td>Ask a doctor</td> </tr> <tr> <td>24-35 lbs.</td> <td>2-3 years</td> <td>2 tablets</td> </tr> <tr> <td>36-47 lbs.</td> <td>4-5 years</td> <td>3 tablets</td> </tr> <tr> <td>48-59 lbs.</td> <td>6-8 years</td> <td>4 tablets</td> </tr> <tr> <td>60-71 lbs.</td> <td>9-10 years</td> <td>5 tablets</td> </tr> <tr> <td>72-95 lbs.</td> <td>11 years</td> <td>6 tablets</td> </tr> </tbody> </table> <p>**or as directed by a doctor</p> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>each tablet contains: calcium 10 mg</li> <li>store between 20-25°C (68-77°F). Avoid high humidity. Protect from light.</li> </ul> <p><b>Inactive ingredients</b></p> <p>acacia gum<sup>1</sup>, calcium carbonate<sup>1</sup>, organic carnauba wax, cellulose<sup>1</sup>, citric acid<sup>1</sup>, dextrose<sup>1</sup>, dibehenin (vegetable source)<sup>2</sup>, flavor<sup>1</sup>, glycerin<sup>1</sup>, grape flavor<sup>1</sup>, organic guar gum, maltodextrin<sup>1</sup>, organic palm olein, organic stevia rebaudiana leaf extract, organic sunflower lecithin, xylitol<sup>1</sup></p> <p><sup>1</sup>natural</p> <p><b>Questions?</b> 1-855-436-3921</p>	Weight	Age	Dose**	Under 24 lbs.	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Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount</p> <ul style="list-style-type: none"> <li>with other drugs containing acetaminophen</li> </ul> <p><b>Allergy alert:</b> acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Certified Gluten Free</p> <p>*This product is not manufactured or distributed by Johnson &amp; Johnson Corp., owner of the registered trademark Children's Tylenol® Chewables Grape.</p> <p>Patent Pending   Distributed by: Genexa Inc. Atlanta, GA 30318   genexa.com</p>	Active ingredient (in each tablet)	Purpose	Acetaminophen 80 mg	Pain reliever/fever reducer
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GENEXA CHILDRENS ACETAMINOPHEN			
acetaminophen tablet, chewable			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69676-0058
<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		
GLYCERIN (UNII: PDC6A3C0OX)			
PALM OIL (UNII: 5QUO05548Z)			
XYLITOL (UNII: VCQ006KQ1E)			
GUAR GUM (UNII: E8911637KE)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)			
CALCIUM CARBONATE (UNII: H0G9379FGK)			

<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>STEVIA REBAUDIUNA LEAF</b> (UNII: 6TC6NN0876)	
<b>LECITHIN, SUNFLOWER</b> (UNII: 834K0WOS5G)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>DEXTROSE</b> (UNII: IY9XDZ35W2)	
<b>ACACIA</b> (UNII: 5C5403N26O)	

### Product Characteristics

<b>Color</b>	white (LIGHT BEIGE WTH SPECKLES)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	20mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	G10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69676-0058-7	1 in 1 CARTON	02/28/2022	
1		24 in 1 BOTTLE; 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	02/28/2022	

**Labeler** - Genexa Inc. (079751024)

Revised: 9/2022

Genexa Inc.