

ACETAMINOPHEN- acetaminophen bar, chewable

Alexso, 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.

Acetaminophen 160 mg Chewable Gels

Acetaminophen 160 mg Soft Chews

Alexso, Inc.

Acetaminophen 160 mg Soft Chews

DRUG FACTS

ACTIVE INGREDIENT

Acetaminophen 160mg

PURPOSE

Pain reliever/fever reducer

USES

Acetaminophen 160mg Soft Chews is used for the temporarily relief of minor aches and pain due to the common cold, flu, headache, sore throat, toothache, and temporarily reduces fever.

WARNINGS

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

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 10 doses in 24 hours
- with other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a physician or pharmacist.
- adults has 3 or more alcoholic drinks every day while using this product

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 other drugs containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a physician or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Take under the supervision of a physician if you have liver disease, taking a blood thinning drug called warfarin, or have a history of high blood pressure or diabetes.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days (for adults) or 5 days (for children)
- 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.

If pregnant or breast-feeding, consult a physician or health professional before use.

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) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DIRECTIONS

Do not take more than directed (see overdose warning)

Adults and children 12 years and over:

- take 4 soft chews every 4 to 6 hours while symptoms last or as directed by a physician
- chew each soft chew thoroughly before swallowing
- do not take more than 20 soft chews in 24 hours
- do not take for more than 10 days unless directed by a physician

Children 6 to 11 years:

- take 2 soft chews every 4 to 6 hours while symptoms last or as directed by a physician
- chew each soft chew thoroughly before swallowing
- do not take more than 10 soft chews in 24 hours
- do not take for more than 5 days unless directed by a physician

Children under 6 years: ask a physician

OTHER INFORMATION

- **each soft chew contains: sodium 7.44 mg.**
- **each soft chew contains: sugar 2g.**
- store in a cool dry place between 20-25°C (68-77°F).

Child Resistant Container; do not use if printed seal under cap is broken or missing.

Inactive ingredients:

hydroxypropyl betadex, seaweed extract (carrageenan), maltitol solution, sugar, sodium citrate, sodium chloride, sucralose, neotame, maltodextrin, glucose syrup, flavor, purified water.

HOW SUPPLIED

Acetaminophen 160mg Soft Chews is supplied in the following dosage form:

Fourteen (14) Soft Chews per container

Made in USA
 Manufactured for:
 Alexso, Inc.
 2317 Cotner Ave
 Los Angeles, CA 90064
 NDC: 50488-4160-1
 Size: 14 Soft Chews

PRINCIPAL DISPLAY PANEL

Acetaminophen 160 mg Soft Chews
 14 Orange Flavored Gummies
 Chewy Gummy Bites
 NDC:50488-4160-1

<p>Acetaminophen 160 mg Soft Chews for Pain Relief & Fever Reducer</p> <p>14 Orange Flavored Gummies</p> <p>★ Ibuprofen Free ★ Aspirin Free</p> <p>CHEWY GUMMY BITES</p> <p>NDC: 50488-4160-1</p>	<p>Drug Facts</p> <p>Active Ingredient (in each soft chew) Acetaminophen 160 mg.....Pain relief/fever reducer</p> <p>Purpose Acetaminophen 160 mg.....Pain relief/fever reducer</p> <p>Uses temporarily relieves minor aches and pain due to: • the common cold • flu • headache • sore throat • toothache • temporarily reduced fever</p> <p>Warnings Liver warning: this product contains acetaminophen. Severe liver damage may occur if: • adult takes more than 4,000 mg of acetaminophen in 24 hours • child takes more than 10 doses in 24 hours • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product</p> <p>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</p> <p>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.</p> <p>Directions Do not take more than directed (see overdose warning) Adults and children 12 years and over: • take 4 soft chews every 4 to 6 hours while symptoms last or as directed by a physician • chew each soft chew thoroughly before swallowing</p> <p>Continued under label</p>
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Alexso inc.
 Manufactured for: Alexso, Inc.
 2317 Cotner Ave, Los Angeles, CA 90064
 50488 41601 6

Lot:
Exp:
 PEEL HERE

<p>Drug Facts (continued)</p> <p>• do not take more than 20 soft chews in 24 hours • do not take for more than 10 days unless directed by a physician</p> <p>Children 6 to 11 years: • take 2 soft chews every 4 to 6 hours while symptoms last or as directed by a physician • chew each soft chew thoroughly before swallowing • do not take more than 10 soft chews in 24 hours • do not take for more than 5 days unless directed by a physician</p> <p>Children under 6 years: ask a physician</p> <p>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 you are allergic to acetaminophen or any of the inactive ingredients in this product</p> <p>Take under the supervision of a physician if you have liver disease, taking a blood thinning drug called warfarin, or have a history of high blood pressure or diabetes.</p> <p>Stop use and ask a doctor if • pain gets worse or lasts more than 10 days (for adults) or 5 days (for children) • 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. If pregnant or breast-feeding, ask a health professional before use.</p> <p>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). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Other information • each soft chew contains: sodium 7.44 mg. • each soft chew contains: sugar 2g. • store in a cool, dry place between 20-25°C (68-77°F). • Child Resistant Container; do not use if printed seal under cap is broken or missing.</p> <p>Inactive ingredients: hydroxypropyl betadex, seaweed extract (carrageenan), maltitol solution, sugar, sodium citrate, sodium chloride, sucralose, neotame, maltitol, glucose syrup, flavor, purified water.</p> <p>Questions or comments? Call 1-888-495-6078</p>
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ACETAMINOPHEN
 acetaminophen bar, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50488-4160
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROXYPROPYL BETADEX (UNII: 1I96OHX6EK)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
MALTITOL (UNII: D65DG142WK)	
SUCROSE (UNII: C151H8M554)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
NEOTAME (UNII: VJ597D52EX)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CORN SYRUP (UNII: 9G5L16BK6N)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	25mm
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-4160-1	14 in 1 CONTAINER; Type 0: Not a Combination Product	11/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	11/01/2019	

Labeler - Alexso, Inc (963338061)