

ACETAMINOPHEN- acetaminophen tablet
NCS HealthCare of KY, Inc dba Vanguard Labs

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 Tablet 500mg

Active ingredient (in each tablet)

Acetaminophen 500 mg

Purposes

Pain Reliever/Fever Reducer

Uses

for the temporary relief of minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen.

The maximum daily dose of this product is 6 tablets (3,000mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

Ask a doctor before use if you have

liver disease.

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 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.

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

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 for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Do not take more than the directed (see overdose warning)

Adults and children 12 years and over:

- Take 2 tablets every 6 hours while symptoms last.
- Do not take more than 6 tablets in 24 hours unless directed by a doctor
- Do not take for more than 10 days unless directed by a doctor

Children under 12 years: Do not use adult Extra Strength product in children under 12 years of age; this will provide more than the recommended dose (overdose) of acetaminophen and may cause liver damage.

Other information

- Store at room temperature

Inactive ingredients

Povidone, Pregelantized Starch, Sodium Starch Glycolate, Stearic Acid.

Questions or comments?

(800) 616-2471

Tamper Evident:

Do not use if sealed blister units are broken or damaged.

Distributed By: MAJOR PHARMACEUTICALS

31778 Enterprise Drive. Livonia, MI 48150 USA

Rev. 02/12 M-95

Principal Display Panel



VLI NDC 0615-4510-39

Acetaminophen
Tabs 500 mg

LOT
4510
EXP
12717-39

QTY
30

Mfg By Gemini for
Major
(NDC 0904-1988-80)
PKG BY VANGARD
GLASGOW, KY 42141

SEE WARNINGS
ON REVERSE

PAIN RELIEVER
FEVER REDUCER

TAMPER
EVIDENT

(Major NDC 0904-1988-80)
Acetaminophen Tabs
500 mg

Received: _____

24	16	8
31	23	7
30	22	6
29	21	5
28	20	4
27	19	3
26	18	2
25	17	1

START DATE _____ START TIME _____

STORE AT 20°-25°C (68°-77°F)
(SEE USP CONTROLLED ROOM TEMPERATURE)

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take more than 4,000 mg of acetaminophen in 24 hours - with other drugs containing acetaminophen - 3 or more alcoholic drinks every day while using this product. 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.

Keep out of the reach of children
See Package Label Binder for full labeling information and additional warnings.
FOR INSTITUTIONAL USE ONLY

16	8
30	7
29	6
28	5
27	4
26	3
25	2
24	1

<p>Pkg By Vanguard, Glasgow, KY 42141 ACETAMINOPHEN TABLET 500 mg</p> <p>LOT 4510</p>	<p>Pkg By Vanguard, Glasgow, KY 42141 ACETAMINOPHEN TABLET 500 mg</p> <p>LOT 4510</p>	<p>Pkg By Vanguard, Glasgow, KY 42141 ACETAMINOPHEN TABLET 500 mg</p> <p>LOT 4510</p>	<p>18422641 01 09041988 005 Glasgow, KY 42141</p> <p>LOT 4510</p>
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The overall configuration of this package is a trademark of Omnicare, Inc.

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0615-4510(NDC:0904-1988)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND (round flat faced beveled edge)	Size	12mm
Flavor		Imprint Code	GPI;A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:06 15-4510-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/04/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/04/2011	

Labeler - NCS HealthCare of KY, Inc dba Vanguard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vanguard Labs		050052943	RELABEL(06 15-4510) , REPACK(06 15-4510)

Revised: 1/2017

NCS HealthCare of KY, Inc dba Vanguard Labs