

HEADACHE FORMULA EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet, film coated

ARMY AND AIR FORCE EXCHANGE SERVICE

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.

Exchange Select 44-334B

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Uses

- temporarily relieves minor aches and pains due to:

- headache
- arthritis
- a cold
- muscular aches
- toothache
- premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product.

When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- shock
- facial swelling
- hives
- asthma (wheezing)

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.

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

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

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much **caffeine** as a cup of coffee. Limit the use of

caffeine-containing medications, foods, or beverages while taking this product because too much **caffeine** may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- 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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- redness or swelling is present
- pain gets worse or lasts for more than 10 days

- fever gets worse or lasts for more than 3 days
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over
 - take 2 caplets every 6 hours
 - do not take more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

exchange[®]select[™]

Compare To The Active Ingredients of Excedrin[®] Extra Strength†

**EXTRA STRENGTH
HEADACHE FORMULA**

Acetaminophen, Aspirin (NSAID) and Caffeine

Pain Reliever / Pain Reliever Aid

Actual Size

100 CAPLETS

quality value

†This product is not manufactured or distributed by Novartis AG, owner of the registered trademark Excedrin® Extra Strength.

50844 REV0418A33412

"SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For Your Military Exchanges

Distributed by: LNK International, Inc.

Hauppauge, NY 11788

1-800-426-9391

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

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

exchange select

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exchange select

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Acetaminophen
Aspirin (NSAID) and Caffeine
Pain Reliever / Pain Reliever Aid

100 CAPLETS

B-0066E-334B-12-R
REV0418A33412

Drug Facts (continued)

- fever gets worse or lasts for more than 3 days
- new symptoms occur
- rash
- severe symptoms occur

These symptoms occur in rare cases of a serious condition called Reye's syndrome.

If pregnant or breastfeeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy or while breastfeeding because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Inactive ingredients corn starch; croscarmellose; hypromellose; microcrystalline cellulose; polydioxane; polyethylene glycol; sodium lauryl sulfate; sodium starch glycolate; stearic acid; titanium dioxide

Questions or comments? 1-800-426-3391

*This product is not manufactured or distributed by Novartis AG, owner of the registered trademark Excedrin® Extra Strength. Manufactured For Your Money Back™ Exchange. Distributed by: LNK International, Inc., Hauppauge, NY 11788 1-800-426-3391

DG1193BR2

Drug Facts (continued)

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.

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- taking any other drug or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
 - ringing in the ears or a loss of hearing occurs
 - redness or swelling is present
- pain gets worse or lasts for more than 10 days

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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- hives
- wheezing
- asthma (breathing)
- facial swelling
- hives

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- skin redness
- blisters
- rash
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acetaminophen, aspirin, caffeine tablet, film coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55301-334 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 250 mg |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | ASPIRIN | 250 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 65 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSPVIDONE (UNII: 2S7830E561) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | 44;334 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55301-334-12 | 1 in 1 CARTON | 03/13/2008 | |
| 1 | | 100 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 | 03/13/2008 | |

Labeler - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | PACK(55301-334) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
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| | | | |
|-------------------------|--|-----------|-------------------------|
| LNK International, Inc. | | 832867894 | MANUFACTURE(5530 1-334) |
|-------------------------|--|-----------|-------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 868734088 | PACK(5530 1-334) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | PACK(5530 1-334) |

Revised: 7/2019

ARMY AND AIR FORCE EXCHANGE SERVICE