

ADVANCED ASPIRIN- aspirin tablet
ADVANCED FIRST AID, 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.

ACTIVE INGREDIENT IN EACH TABLET- ASPIRIN 325 MG

PAIN RELIEVER/FEVER REDUCER

Uses:

temporarily relieves minor pain due to: • headache • menstrual pain • minor pain of arthritis • muscle pain • pain and fever of colds • toothache • temporarily reduces fever

Uses:

temporarily relieves minor pain due to: • headache • menstrual pain • minor pain of arthritis

•

muscle pain • pain and fever of colds • toothache • temporarily reduces fever

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: • hives • facial swelling

•

asthma (wheezing) • shock

Stomach Bleeding Warning:

This product contains nonsteroidal anti-inflammatory drugs (NSAIDs), which may cause severe stomach bleeding. The chance is higher if you:

• are age 60 or older • have

had stomach ulcers or bleeding problems

• take a blood thinning (anticoagulant) or steroid drug • take

other drugs prescription or nonprescription containing an NSAID [aspirin, ibuprofen, naproxen, or others]

• take more or for a longer time than directed.

Do not use:

• if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if:

- 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 are taking a diuretic • you have a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug for: • gout

- diabetes • arthritis

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:
- you feel faint, vomit blood, or have bloody or black stools
- redness or swelling is present • pain gets worse or lasts more than 10 days • fever lasts more than 3 days
- new symptoms occur • ringing in the ears or a loss of hearing occurs

If pregnant or breast-feeding baby, ask a health professional

before use. IT IS ESPECIALLY IMPORTANT NOT TO USE ASPIRIN DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFIC-ALLY 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 overdose, get medical help or contact a Poison Control Center 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:

- Drink a full glass of water with each dose

Adults and children 12 years OR OLDER :TAKE 2 TABLETS EVERY 4-6 HOURS AS needed, do not exceed 12 tablets in

24 hours, or as directed by a doctor.

Children under 12 YEARS OF AGE

- consult a doctor

Inactive Ingredients:

microcrystalline cellulose,
povidone, pregelatinized starch

Pain Reliever/Fever Reducer
Alivia el Dolor/Reduce la Fiebre



Product #1112

100 Tablets • 2 Tablets Per Packet

Drug Facts

Active ingredient (in each tablet)
Aspirin 325 mg (NSAID)¹.....**Purpose**
pain reliever/fever reducer
¹nonsteroidal anti-inflammatory drug

Uses: temporarily relieves minor pain due to: • headache • menstrual pain • minor pain of arthritis
• muscle pain • pain and fever of colds • toothache • temporarily reduces fever

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: • hives • facial swelling • asthma (wheezing) • shock

Stomach Bleeding Warning: This product contains nonsteroidal anti-inflammatory drugs (NSAIDs), which may cause severe stomach bleeding. The chance is higher if you: • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or steroid drug • take other drugs, prescription or nonprescription containing an NSAID (aspirin, ibuprofen, naproxen, or others) • take more or for a longer time than directed.

Do not use: • if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if: • 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 are taking a diuretic • you have a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug for: • gout • diabetes • arthritis

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: • you feel faint, vomit blood, or have bloody or black stools • redness or swelling is present • pain gets worse or lasts more than 10 days • fever lasts more than 3 days • new symptoms occur • ringing in the ears or a loss of hearing occurs

Product #1112



Pain Reliever/Fever Reducer
Alivia el Dolor/Reduce la Fiebre



Pain Reliever/Fever Reducer (NSAID)

PULL TO OPEN

- Temporary relief from pain and fever
- Soothes muscle aches and minor arthritis pain

Drug Facts (continued)

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 SPECIFICALLY 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 overdose, get medical help or contact a Poison Control Center 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: • Drink a full glass of water with each dose.

Adults and children 12 years of age or older:	• take 2 tablets every 4 to 6 hours as needed, do not exceed 12 tablets in 24 hours, or as directed by a doctor.
Children under 12 years of age:	• consult a doctor

Other information:

- Tamper Evident: Do not use if packet is torn, cut or opened.
- Store at controlled room temperature 15° to 30°C (59° to 86°F)
- Avoid excessive heat and humidity.

Inactive ingredients: microcrystalline cellulose, povidone, pregelatinized starch

Do not use if individual packet is open or torn.

100 Tablets • 2 Tablets Per Packet

Manufactured For:
Advanced First Aid, Baltimore, MD 21237
www.advanced1staid.com • 1-888-922-5678



PACKAGED
IN THE USA

TAMPER EVIDENT: DO NOT USE IF PACKET IS TORN OR CUT.



Pain Reliever/Fever Reducer (NSAID)

Each tablet contains: Aspirin.....325 mg(NSAID)*
*nonsteroidal anti-inflammatory drug

USES: For the temporary relief of headache, menstrual pain, minor pain of arthritis, muscle pain, pain and fever of colds, toothache, temporarily reduces fever

2 TABLETS PER PACKET

WARNINGS: Reye's Syndrome: Children and teenagers who have or are recovering from chicken pox or flu 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: hives, facial swelling, asthma (wheezing), shock. **Stomach Bleeding Warning:** This product contains a nonsteroidal anti-inflammatory drugs (NSAIDs), which may cause severe stomach bleeding. The chance is higher if you: ■ are age 60 or older ■ have had stomach ulcers or bleeding problems ■ take a blood thinning (anticoagulant) or steroid drug ■ take with other drugs containing an NSAID [aspirin, ibuprofen, naproxen, or others] ■ take more or for a longer time than directed. **KEEP OUT OF REACH OF CHILDREN. DIRECTIONS:** Adults and children 12 years of age and older: 2 tablets every 4 to 6 hours, do not exceed 12 tablets in 24 hours. Children under 12 consult a physician. Store at controlled room temperature 15° to 30°C (59° to 86°F).

Additional Warnings/Cautions: See Box

**Mfg. for: Advanced First Aid, Baltimore, MD 21237
American Safety & First Aid Osceola, IN 46561**

ADVANCED ASPIRIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67060-232
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (SNOW WHITE)	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67060-232-68	100 in 1 CARTON	04/07/2015	
1	NDC:67060-232-02	2 in 1 PACKET; 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	04/07/2015	

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-232)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-232)

Revised: 4/2015

ADVANCED FIRST AID, INC.