

ASPIRIN 5 GRAIN- aspirin tablet
Provision Medical Products

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.

Uses:

temporarily relieves pains due to:•headache • minor pain of arthritis•muscular aches • temporarily reduces fever•common cold

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.

Warnings:

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or -u symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers.

Aspirin may cause stomach bleeding.

Do not use:

-

if you are allergic to aspirin

- with any other pain reliever/fever reducer

- if you have ever had an allergic reaction to any other pain reliever/fever reducer

- for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor

- with any other product containing aspirin

Ask a doctor before using if you have:

- asthma • gastric ulcers • bleeding problems

- stomach problems (such as heartburn, upset stomach or stomach pain)

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

- anticoagulation
(thinning of blood)

- diabetes • gout • arthritis

Stop use and ask a doctor if:

- ringing in the ears or loss of hearing occurs

- pain or fever persists or gets worse

- new symptoms occur

- redness or swelling is present

When using this product do not exceed recommended dose

Directions:

Adults and children 12 years of age and 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 consult a

doctor.

Do not use more than directed

Inactive Ingredients:

corn starch, povidone, silicon dioxide
and stearic acid.

ACTIVE INGREDIENT-ASPIRIN 325 MG

PAIN RELIEVER/FEVER REDUCER





ASPIRIN 5 GRAIN

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 103-250 1
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-2501-5	250 in 1 CARTON	04/03/2015	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69103-2501-6	100 in 1 CARTON	04/03/2015	
2		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	03/31/2015	

Labeler - Provision Medical Products (036936831)

Registrant - Provision Medical Products (036936831)

Establishment

Name	Address	ID/FEI	Business Operations
Ultraseal Corporation		085752004	pack(69103-2501)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(69103-2501)

Revised: 10/2019

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