

ASPIRIN CHEWABLE- aspirin 81 mg tablet
McKesson Corporation dba SKY Packaging

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.

Drug Facts

Active ingredient

Aspirin 81 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporary relief of minor aches and pains or as recommended by your doctor

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 an NSAID, 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 containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ 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 this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

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 asthma

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: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

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 accidental overdose, get medical help or contact a Poison Control Center(1-800-222-1222) immediately.

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Inactive Ingredients

corn starch, dextrans, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium

HOW SUPPLIED

Product: 63739-434

NDC: 63739-434-01 30 TABLET in a BLISTER PACK / 25 in a BOX, UNIT-DOSE

Drug Facts



6373943-01

NDC 63739-434-01

Aspirin Chewable Tablets, 81 mg (NSAID)*

Compare to Bayer® active ingredient
UD 750 Tablets (25X30)

U.S. Pat. No. 7,616,999; Packaging Services a business unit of McKesson Corporation
7100 Washington Blvd., Cincinnati, OH 45240



6373943-01

NDC 63739-434-01

Aspirin Chewable Tablets, 81mg

Drug Facts

Active ingredient in each tablet:

Aspirin

Other active ingredients:

Aspirin 81 mg

Non-aspirin analgesic/antipyretic drug

Low-dose aspirin may reduce the risk of heart disease and stroke in some people. See your doctor for more information.

Warnings

Heart and stroke warning: Aspirin and aspirin products may increase the risk of heart disease and stroke. If you have a history of heart disease or stroke, or if you are taking aspirin for a heart condition, you should take aspirin with caution. See your doctor for more information.

Aspirin allergy warning: Aspirin and aspirin products may cause allergic reactions in some people. If you have a history of allergic reactions to aspirin, you should avoid aspirin. See your doctor for more information.

Aspirin and other drugs warning: Aspirin and aspirin products may interact with other drugs. Tell your doctor if you are taking any other drugs, including over-the-counter drugs, prescription drugs, and herbal products.

Aspirin and alcohol warning: Aspirin and aspirin products may increase the risk of stomach bleeding and ulcers if you drink alcohol. See your doctor for more information.

Aspirin and surgery warning: Aspirin and aspirin products may increase the risk of bleeding during surgery. Tell your doctor if you are taking aspirin before surgery.

Aspirin and pregnancy warning: Aspirin and aspirin products may increase the risk of complications during pregnancy. Tell your doctor if you are pregnant or planning to get pregnant.

Aspirin and breastfeeding warning: Aspirin and aspirin products may pass into breast milk. Tell your doctor if you are breastfeeding your child.

Aspirin and other health conditions warning: Aspirin and aspirin products may increase the risk of complications in people with certain health conditions, such as liver disease, kidney disease, and stomach ulcers. See your doctor for more information.

Aspirin and other medications warning: Aspirin and aspirin products may interact with other medications. Tell your doctor if you are taking any other medications.

Aspirin and other products warning: Aspirin and aspirin products may interact with other products. Tell your doctor if you are using any other products.

Aspirin and other substances warning: Aspirin and aspirin products may interact with other substances. Tell your doctor if you are using any other substances.

Aspirin and other activities warning: Aspirin and aspirin products may affect your ability to perform certain activities. Tell your doctor if you are engaged in any activities.

Aspirin and other risks warning: Aspirin and aspirin products may increase the risk of certain risks. See your doctor for more information.

Aspirin and other side effects warning: Aspirin and aspirin products may cause certain side effects. See your doctor for more information.

Aspirin and other symptoms warning: Aspirin and aspirin products may cause certain symptoms. See your doctor for more information.

Aspirin and other conditions warning: Aspirin and aspirin products may cause certain conditions. See your doctor for more information.

Aspirin and other problems warning: Aspirin and aspirin products may cause certain problems. See your doctor for more information.

Aspirin and other issues warning: Aspirin and aspirin products may cause certain issues. See your doctor for more information.

Aspirin and other concerns warning: Aspirin and aspirin products may cause certain concerns. See your doctor for more information.

Aspirin and other matters warning: Aspirin and aspirin products may cause certain matters. See your doctor for more information.

Aspirin and other topics warning: Aspirin and aspirin products may cause certain topics. See your doctor for more information.

Aspirin and other subjects warning: Aspirin and aspirin products may cause certain subjects. See your doctor for more information.

Aspirin and other objects warning: Aspirin and aspirin products may cause certain objects. See your doctor for more information.

Aspirin and other instances warning: Aspirin and aspirin products may cause certain instances. See your doctor for more information.

Aspirin and other circumstances warning: Aspirin and aspirin products may cause certain circumstances. See your doctor for more information.

Aspirin and other situations warning: Aspirin and aspirin products may cause certain situations. See your doctor for more information.

Aspirin and other events warning: Aspirin and aspirin products may cause certain events. See your doctor for more information.

Aspirin and other occasions warning: Aspirin and aspirin products may cause certain occasions. See your doctor for more information.

Aspirin and other times warning: Aspirin and aspirin products may cause certain times. See your doctor for more information.

Aspirin and other periods warning: Aspirin and aspirin products may cause certain periods. See your doctor for more information.

Aspirin and other parts warning: Aspirin and aspirin products may cause certain parts. See your doctor for more information.

Aspirin and other components warning: Aspirin and aspirin products may cause certain components. See your doctor for more information.

Aspirin and other elements warning: Aspirin and aspirin products may cause certain elements. See your doctor for more information.

Aspirin and other details warning: Aspirin and aspirin products may cause certain details. See your doctor for more information.

Aspirin and other information warning: Aspirin and aspirin products may cause certain information. See your doctor for more information.

Aspirin and other knowledge warning: Aspirin and aspirin products may cause certain knowledge. See your doctor for more information.

Aspirin and other understanding warning: Aspirin and aspirin products may cause certain understanding. See your doctor for more information.

Aspirin and other awareness warning: Aspirin and aspirin products may cause certain awareness. See your doctor for more information.

Aspirin and other realization warning: Aspirin and aspirin products may cause certain realization. See your doctor for more information.

Aspirin and other perception warning: Aspirin and aspirin products may cause certain perception. See your doctor for more information.

Drug Facts

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Active ingredient (in each tablet) **Purpose**

Aspirin 81 mg (NSAID*) Pain Reliever

*nonsteroidal anti-inflammatory drug

Uses temporary relief of minor aches and pains or as recommended by your doctor

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

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Do not use if you are allergic to aspirin or any other pain reliever/fever reducer • this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

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 asthma

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: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better • pain gets worse or lasts more than 10 days • redness or swelling is present • new symptoms occur • ringing in the ears or loss of hearing occurs

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions • drink a full glass of water with each dose • adults and children 12 years and over: take 4 to 6 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor • children under 12 years: consult a doctor

Other information • save carton for full directions and warnings • store at room temperature • do not use if blister card is damaged or appears to have been tampered

Inactive ingredients corn starch, dextrates, FD&C yellow #6 aluminum lake, orange flavor, saccharin sodium

Mfg. By: Allegiant Health, Deer Park, NY 11729

Dist. By: McKesson Corporation, Memphis, TN 38141

*This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Bayer®



NDC 63739-434-02

ASPIRIN CHEWABLE



Tablets, 81 mg (NSAID*)
UD 300 Tablets (30x10)

LOT 1234567890

EXP YYYY-MM-DD



(01)10363739434025

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ASPIRIN CHEWABLE

aspirin 81 mg tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63739-434(NDC:69168-288)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
DEXTRATES (UNII: G263MI44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	7mm
Flavor	ORANGE	Imprint Code	AZ013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-434-01	25 in 1 BOX, UNIT-DOSE	08/02/2016	05/31/2021
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63739-434-02	30 in 1 BOX	03/18/2021	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	12/18/2014	

Labeler - McKesson Corporation dba SKY Packaging (140529962)

Establishment

Name	Address	ID/FEI	Business Operations
Legacy Pharmaceutical Packaging, LLC		143213275	repack(63739-434) , relabel(63739-434)

