

## **ADULT LOW STRENGTH ASPIRIN- aspirin tablet, coated**

### **Safeway**

*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.*

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### **Safeway 44-414A-Delisted**

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

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

#### **Purpose**

Pain reliever

#### **Uses**

temporarily relieves minor aches and pains

#### **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
- shock
- facial swelling
- asthma (wheezing)

**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 have ever had an allergic reaction to any pain reliever or 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 have asthma
- you are taking a diuretic

**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**

- 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
- and allergic reaction occurs
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present

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 overdose, get medical help or contact a Poison Control Center right away.

**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 while symptoms persist. Do not exceed 48 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use unless directed by a doctor

**Other information**

- store at controlled room temperature 15°-30°F (59°-86°F)
- see end flap for expiration date and lot number

**Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?**

1-877-932-7948

**Principal Display Panel**

NDC 21130-414-12

**Compare to St. Joseph® Adult Low Strength** active ingredient†

**Adult Low Strength  
Aspirin 81 mg (NSAID)**

Aspirin Tablets, 81 mg

- Enteric Coated
- Pain Reliever

100 TABLETS

**SAFEWAY™**

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

50844 REV0512B41412

DISTRIBUTED BY SAFEWAY INC.

P.O. BOX 99, PLEASANTON, CA 94566-0009



Safeway 44-414A

## ADULT LOW STRENGTH ASPIRIN

aspirin tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-414
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
Polyvinyl Acetate Phthalate (UNII: 58QVG85GW3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

### Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	44;414
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-414-12	1 in 1 CARTON		
1		100 in 1 BOTTLE, PLASTIC; 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	01/14/2004	05/27/2018

**Labeler** - Safeway (009137209)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(21130-414)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(21130-414)

