ASPIRIN- aspirin tablet
Advance Pharmaceutical 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.

ENTERIC COATED ASPIRIN 81mg

Active Ingredient

(in each tablet)

Aspirin 81 mg (NSAID) *

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

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 signs of Reye's syndrome, a rare but serious illness.

Allergy Alert: Aspirin may cause a severe allergic reaction which may include

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

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
- takes other drugs containing prescription or nonprescription NSAIDs (ibuprofen, naproxen, others)
- takes more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product.

Do not use

- if you have ever had an allergic reaction to 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, lever 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 diabetes, gout or arthritis
- taking any other drug
- under a doctor's care for any serious condition

Stop use and ask a doctor if

- you experiences 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
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- ringing in the ears or a 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 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 older :** take 4 to 8 tablets every 4 hours while symptoms last, but not more than 48 tablets in 24 hours.
- **Children under 12 years:** ask a doctor

Other Information

- store at 15-30 °C (59-86 °F)

Inactive Ingredients

croscarmellose sodium, D&C Yellow #10 (Al-Lake), HPMC, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, propylene glycol, PVP, silicon dioxide, sodium lauryl sulfate, corn starch, stearic acid, talc, titanium dioxide

Questions or Comments

Call 631-981-4600, 8.30am – 4.30 pm ET Monday-Friday

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

Safer for your stomach than pain or Buffered Aspirin

Manufactured by: Advance Pharmaceutical, Inc. Holtsville, NY 11742

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Advance Pharmaceutical Inc.

Adult Low Strength
Pain Reliever
120 TABLETS

Enteric Coated
ASPIRIN (NSAID)
81 mg

*Compare to active ingredient in BAYER® Adult Low Strength Enteric Coated Aspirin

SEE NEW WARNINGS INFORMATION

NDC 17714-121-12

Drug Facts

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

Aspirin 81 mg (NSAID)* ..... Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

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- take other drugs containing prescription or non-prescription NSAIDs (ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer ▶

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

*Advance Pharmaceutical Inc. is not affiliated with the owner of the trademark BAYER®.

Manufactured by: Advance Pharmaceutical Inc.
Holtsville, NY 11742, USA

Lot No.:

Exp. Date:

PEEL HERE FOR MORE DRUG FACTS

0 17714 12112 9

LA1112

Drug Facts (continued)

Ask a doctor before use if

- stomach bleeding warning applies to you
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Other information

- store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients croscarmellose sodium, D&C yellow #10 (Al-lake), HPMC, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol, propylene glycol, PVP, silicon dioxide, sodium lauryl sulfate, corn starch, stearic acid, talc, titanium dioxide

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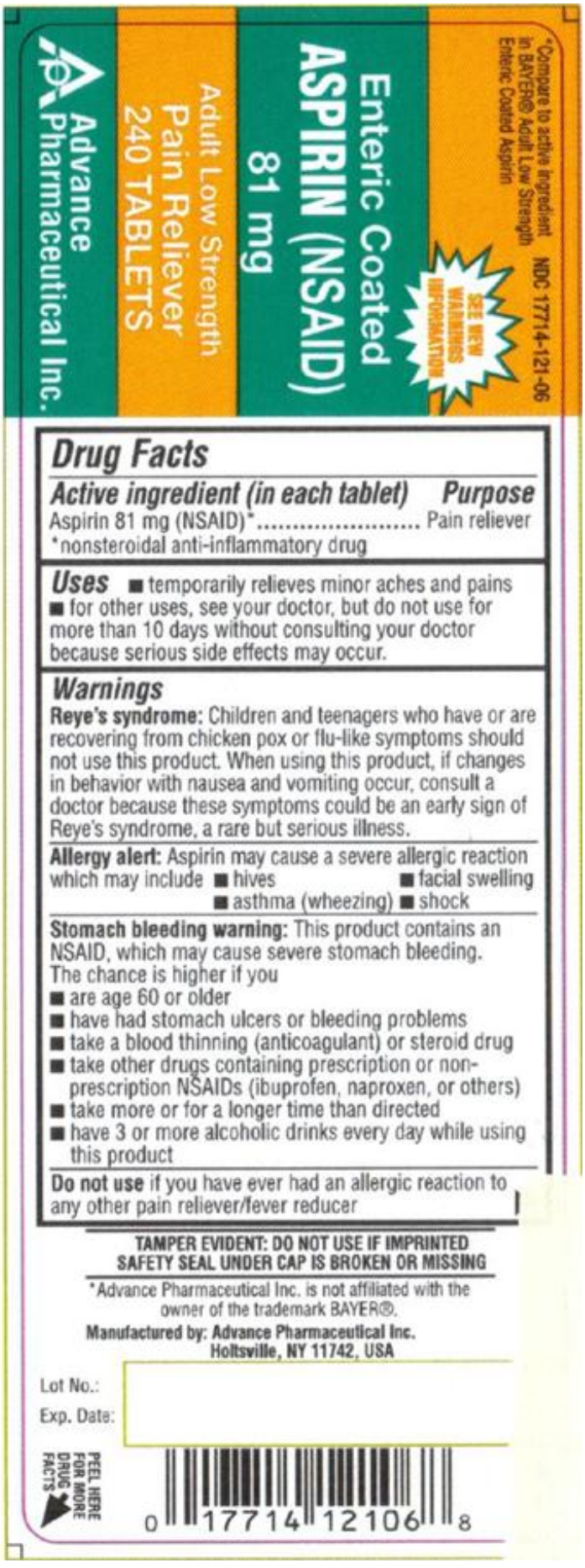
Advance Pharmaceutical Inc.
Enteric Coated
ASPIRIN (NSAID)
81 mg
Adult Low Strength
Pain Reliever
240 TABLETS
*Compare to active ingredient in BAYER® Adult Low Strength Enteric Coated Aspirin
SEE NEW WARNINGS INFORMATION
NDC 17714-121-06
Drug Facts
Active ingredient (in each tablet) Purpose
Aspirin 81 mg (NSAID)* ..... Pain reliever
*nonsteroidal anti-inflammatory drug
Uses ■ temporarily relieves minor aches and pains ■ for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.
Warnings
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Manufactured by: Advance Pharmaceutical Inc.
Holtsville, NY 11742, USA
Lot No.:
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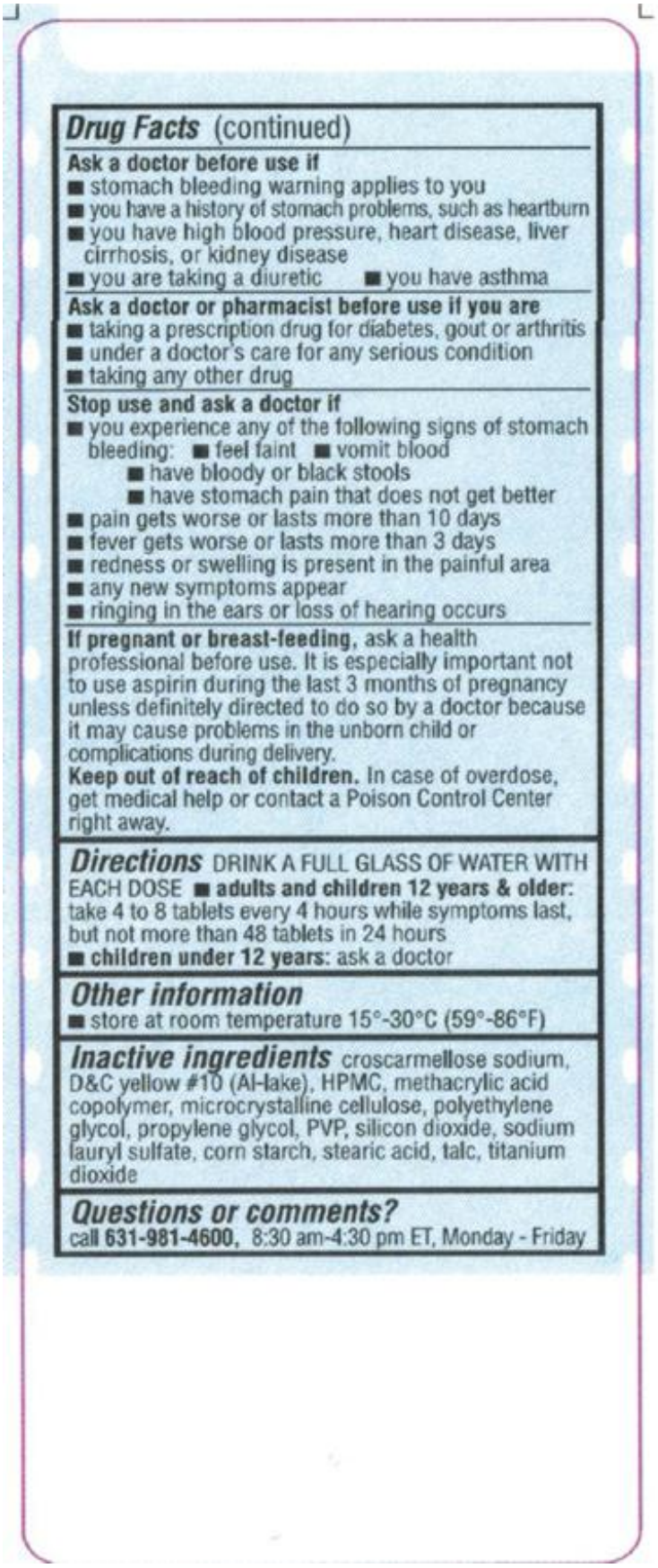
PEEL HERE FOR MORE DRUG FACTS
0 17714 12106 8



Drug Facts (continued)

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NDC: 17714-121-12 – 120 Tablets

NDC: 17714-121-06 - 240 Tablets

ASPIRIN

aspirin tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17714-121
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	AP;121
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17714-121-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2013	
2	NDC:17714-121-06	240 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2013	
3	NDC:17714-121-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part343	06/12/1999	

Labeler - Advance Pharmaceutical Inc. (078301063)

Registrant - Advance Pharmaceutical Inc. (078301063)

Establishment

Name	Address	ID/FEI	Business Operations
Advance Pharmaceutical Inc.		078301063	manufacture(17714-121)

Revised: 10/2017 Advance Pharmaceutical Inc.