

ASPIRIN- aspirin tablet

HART Health

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.

ASPIRIN

Aspirin (NSAID)* 325mg (*non-steroidal anti-inflammatory drug)

Pain Reliever/Fever Reducer

Uses:

Temporarily relieves minor aches and pains due to:

- headache
- backache
- muscular aches
- minor arthritis pain
- common cold
- toothache
- menstrual cramps

Temporarily reduces fever

Warnings:

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

Allergy alert: Aspirin may cause a several 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 more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, others)
- 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 are taking a diuretic
- you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease

Ask a doctor or pharmacist before use if you:

- take any other drug containing an NSAID
- take a blood thinning (anticoagulant) or steroid drug
- take any drug for diabetes, gout, or arthritis

Stop use and ask a doctor if:

- an allergic reaction occurs, seek medical help right away
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- new symptoms occur
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

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. 1-800-222-1222

Directions:

Do not take more than directed.

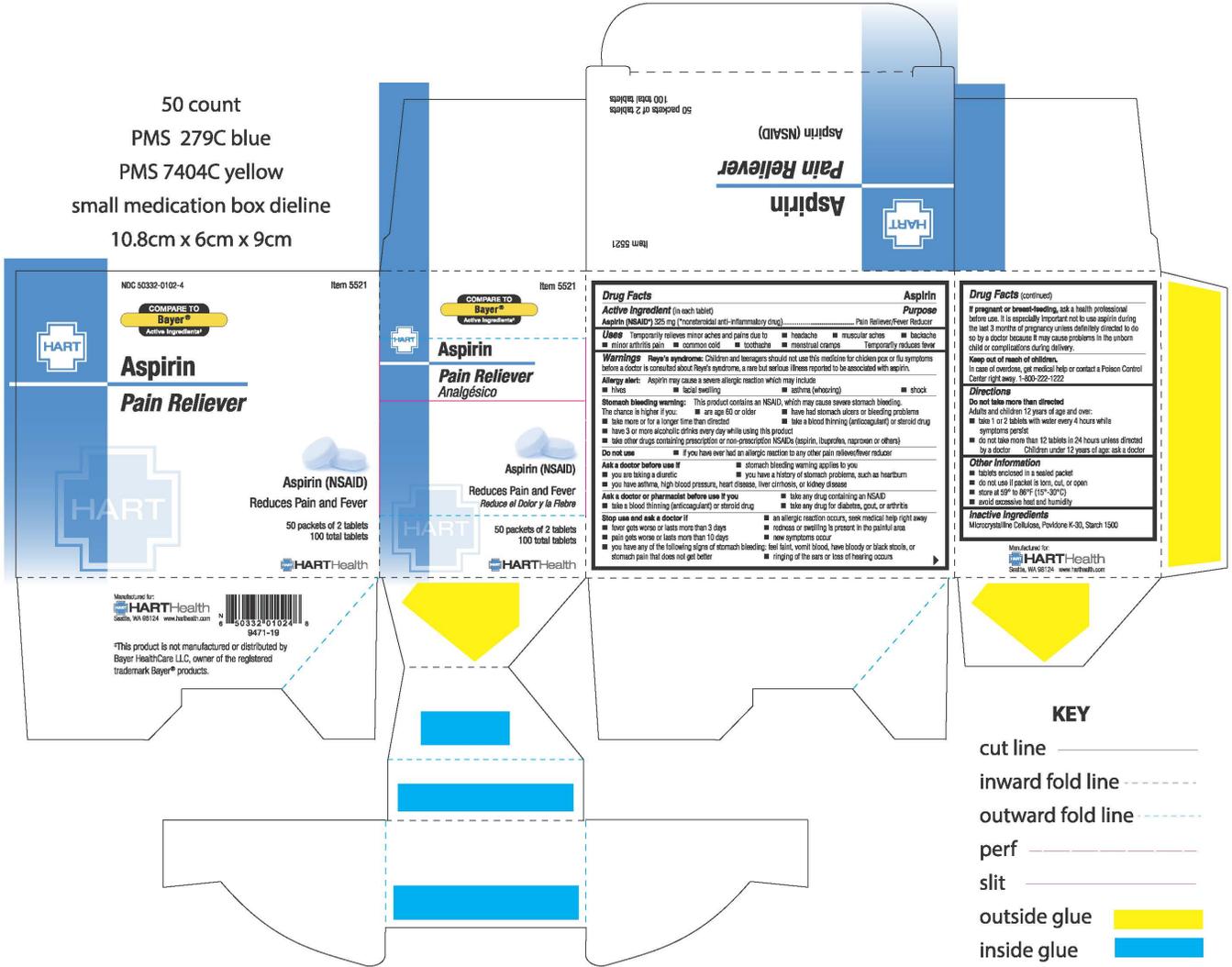
Adults and children 12 years of age and over:

- take 1 or 2 tablets with water every 4 hours while symptoms persist
- do not take more than 12 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

Inactive Ingredients: Microcrystalline Cellulose, Povidone K-30, Starch 1500

50 count
 PMS 279C blue
 PMS 7404C yellow
 small medication box dieline
 10.8cm x 6cm x 9cm



NDC 50332-0102-4

Item 5521

COMPARE TO
Bayer®
 Active Ingredient*

Aspirin
Pain Reliever

Aspirin (NSAID)
 Reduces Pain and Fever

50 packets of 2 tablets
 100 total tablets

HART Health

Manufactured for
HART Health
 Seattle, WA 98124 www.harthealth.com



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Item 5521

COMPARE TO
Bayer®
 Active Ingredient*

Aspirin
Pain Reliever
Analgésico

Aspirin (NSAID)
 Reduces Pain and Fever
 Reduce el Dolor y la Fiebre

50 packets of 2 tablets
 100 total tablets

HART Health

Drug Facts

Active Ingredient (in each tablet)
 Aspirin (NSAID)* 325 mg (Nonsteroidal anti-inflammatory drug) Pain Reliever/Fever Reducer

Warnings **Reye's syndrome:** Children and teenagers should not use this medicine for children's pain or flu symptoms unless a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
 ■ are age 65 or older
 ■ have had stomach ulcers or bleeding problems
 ■ take aspirin or for a longer time than directed
 ■ have 3 or more alcoholic drinks every day while using this product
 ■ take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen or others)

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

Stop use and ask a doctor if
 ■ fever gets worse or lasts more than 3 days
 ■ pain gets worse or lasts more than 10 days
 ■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

Other warnings:
 ■ have had stomach ulcers or bleeding problems
 ■ take a blood thinning (anticoagulant) or steroid drug
 ■ you are taking a diuretic
 ■ you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease
 ■ you have a history of stomach problems, such as heartburn

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

Ask a doctor before use if
 ■ you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease
 ■ you are taking a diuretic
 ■ you have a history of stomach problems, such as heartburn

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

Stop use and ask a doctor if
 ■ fever gets worse or lasts more than 3 days
 ■ pain gets worse or lasts more than 10 days
 ■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

Aspirin

Purpose

Pain Reliever/Fever Reducer

Uses

Temporarily relieves minor aches and pains (due to

minor arthritis pain ■ common cold ■ headache ■ muscle aches ■ backache

menstrual cramps ■ toothache ■ temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers should not use this medicine for children's pain or flu symptoms unless a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

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 65 or older ■ have had stomach ulcers or bleeding problems

■ take aspirin or for a longer time than directed ■ take a blood thinning (anticoagulant) or steroid drug

■ have 3 or more alcoholic drinks every day while using this product ■ take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen or others)

Do not use

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

Ask a doctor before use if

■ you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease

■ you are taking a diuretic ■ you have a history of stomach problems, such as heartburn

Do not use

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

Stop use and ask a doctor if

■ fever gets worse or lasts more than 3 days

■ pain gets worse or lasts more than 10 days

■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

■ see symptoms occur

■ an allergic reaction occurs, seek medical help right away

■ rashness or swelling is present in the painful area

■ see symptoms occur

■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

■ see symptoms occur

■ an allergic reaction occurs, seek medical help right away

■ rashness or swelling is present in the painful area

■ see symptoms occur

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 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: 1-800-222-1222.

Directions

Do not take more than directed.

Adults and children 12 years of age and over:

■ take 1 or 2 tablets with water every 4 hours while symptoms persist

■ do not take more than 12 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor.

Other Information

■ tablets enclosed in a sealed packet

■ do not use if packet is torn, cut, or open

■ store at 68°F to 86°F (20°-30°C)

■ avoid excessive heat and humidity

Inactive Ingredients

Microcrystalline Cellulose, Polydione K-30, Starch 1500

Manufactured for
HART Health
 Seattle, WA 98124 www.harthealth.com

KEY

cut line _____

inward fold line - - - - -

outward fold line - · - · -

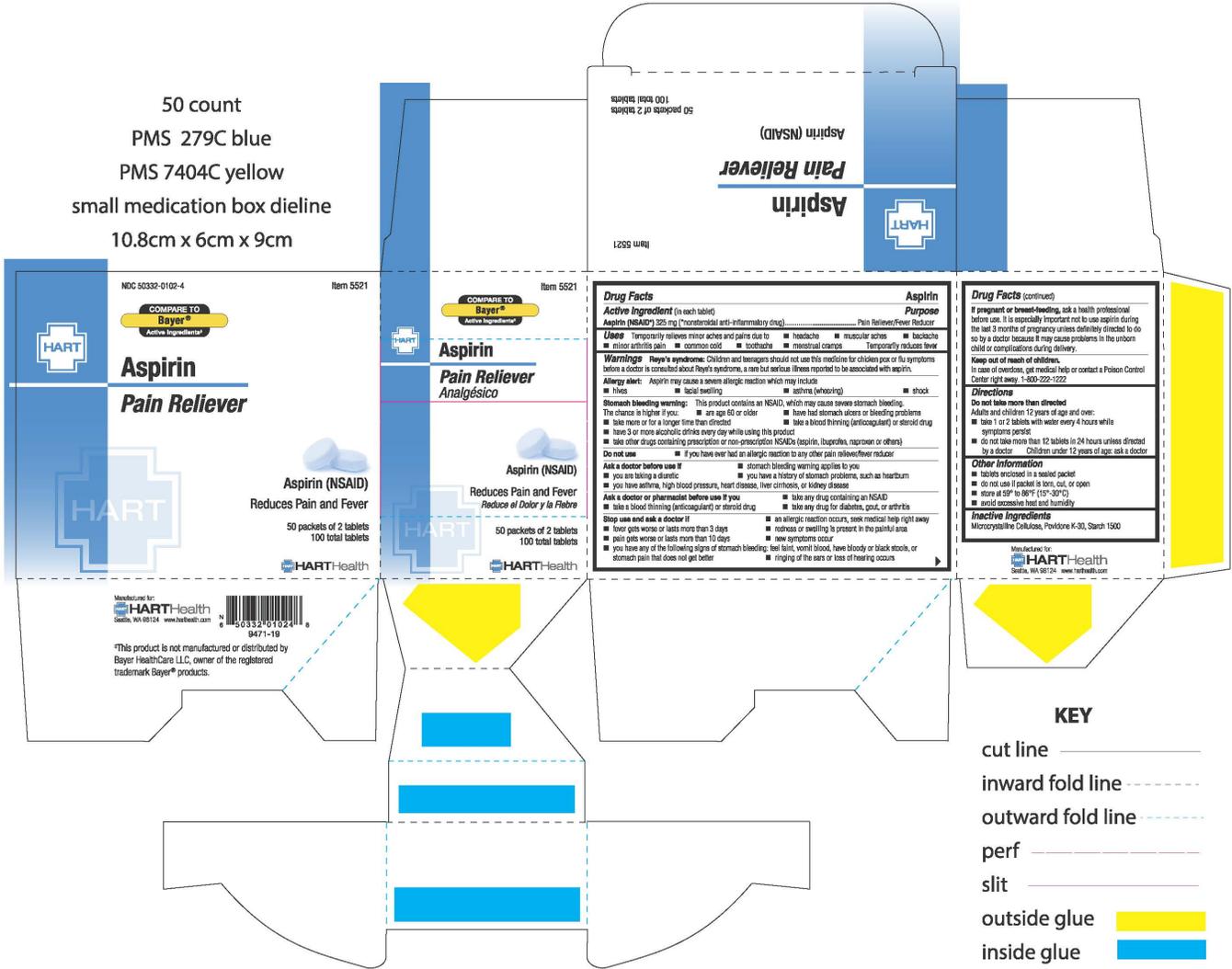
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Aspirin (NSAID)
 Reduces Pain and Fever
 50 packets of 2 tablets
 100 total tablets

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

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

Stop use and ask a doctor if
 ■ fever gets worse or lasts more than 3 days
 ■ pain gets worse or lasts more than 10 days
 ■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

Other warnings:
 ■ throat irritation
 ■ dizziness
 ■ ringing of the ears or loss of hearing occurs

Aspirin

Purpose

Pain Reliever/Fever Reducer

Uses

Temporarily relieves minor aches and pains (due to minor arthritis pain) ■ common cold ■ headache ■ muscle aches ■ backache ■ menstrual cramps ■ toothache ■ Temporarily reduces fever

Warnings

■ shock
 ■ asthma (whooping)

Directions

Do not take more than directed
 Adults and children 12 years of age and over:
 ■ take 1 or 2 tablets with water every 4 hours while symptoms persist
 Do not take more than 12 tablets in 24 hours unless directed by a doctor. Children under 12 years of age: ask a doctor.

Other Information

■ tablets enclosed in a sealed packet
 ■ do not use if packet is torn, cut, or open
 ■ store at 68°F to 86°F (20°-30°C)
 ■ avoid excessive heat and humidity

Inactive Ingredients

Microcrystalline Cellulose, Polydione K-30, Starch 1500

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 definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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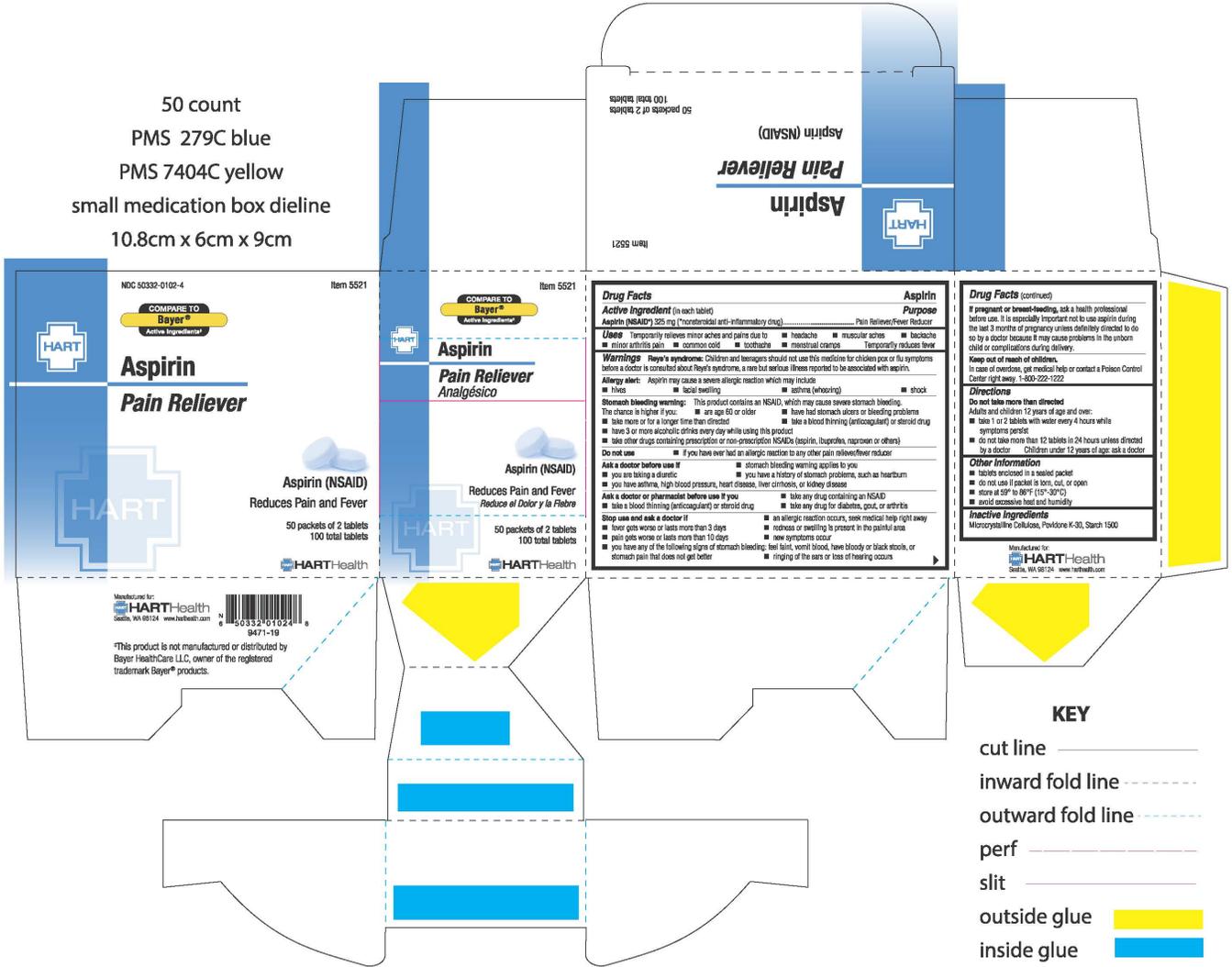
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 ■ have 3 or more alcoholic drinks every day while using this product
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Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
 ■ you are taking a diuretic ■ you have a history of stomach problems, such as heartburn
 ■ you have asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease
 ■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better ■ ring of the ears or loss of hearing occurs

Stop use and ask a doctor if
 ■ you get worse or lasts more than 3 days
 ■ pain gets worse or lasts more than 10 days
 ■ you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better

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Uses

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Directions

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Adults and children 12 years of age and over:

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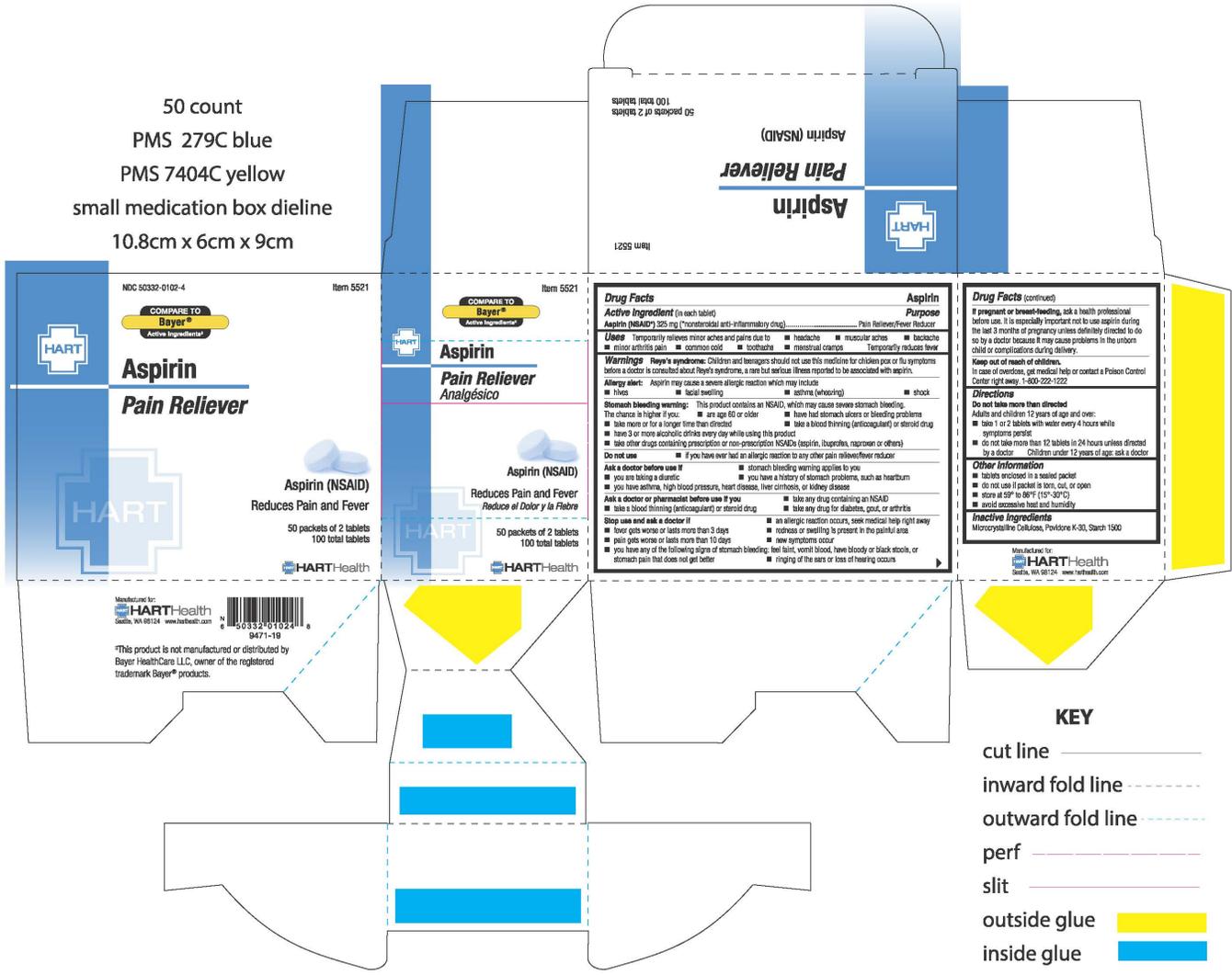
outward fold line

perf - - - - -

slit _____

outside glue

inside glue



ASPIRIN
aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 332-0 10 2
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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 1U)	
MINERAL OIL (UNII: T5L8T28FGP)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	TCL011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0102-4	50 in 1 BOX, UNIT-DOSE	06/04/1986	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0102-7	125 in 1 BOX, UNIT-DOSE	06/04/1986	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0102-8	250 in 1 BOX, UNIT-DOSE	06/04/1986	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0102-3	25 in 1 BOX, UNIT-DOSE	06/04/1986	
4		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 final	part343	06/04/1986	

Labeler - HART Health (069560969)

Revised: 11/2019

HART Health