

CHEWABLE ADULT LOW DOSE ASPIRIN- aspirin tablet, chewable
Raritan Pharmaceuticals 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.

DRx. Choice Chewable Aspirin

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

for the 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 over
- 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

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, 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 not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

- store at room temperature
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, dextrose, FD&C yellow #6 aluminum lake, flavors, maltodextrin, sucralose.

Principal Display Panel

DRxChoice

compare to Bayer® Chewable Low Dose Aspirin active ingredients**

NDC 68163-081-91

low dose

CHEWABLE ASPIRIN

81 mg tablets

pain reliever (**NSAID**)

orange flavor

aspirin regimen

36 Chewable Tablets

3 bottles - 36 tablets each

value pack

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

**This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Bayer® Chewable Low Dose Aspirin.

GLUTEN-FREE (less than 20ppm gluten. If you have specific dietary needs you should consult a doctor before consuming this product.

Distributed By:

Raritan Pharmaceuticals Inc

8 Joanna Court

ASPIRIN Display artwork-1

DR CHOICE®

Low Dose

CHEWABLE ASPIRIN

81mg Tablets • Pain Reliever (NSAID)

Aspirin Regimen**

Orange Flavor

36 Chewable Tablets

DR CHOICE®

Low Dose

CHEWABLE ASPIRIN

81mg Tablets • Pain Reliever (NSAID)

Aspirin Regimen**

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CHEWABLE ASPIRIN

81mg Tablets • Pain Reliever (NSAID)

Aspirin Regimen**

Orange Flavor

36 Chewable Tablets

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

**Aspirin is not appropriate for everyone, so be sure to talk to your doctor before you begin an aspirin regimen.

*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Bayer Chewable Aspirin

GLUTEN-FREE (less than 20ppm gluten). If you have specific dietary needs, you should consult a doctor before consuming this product.

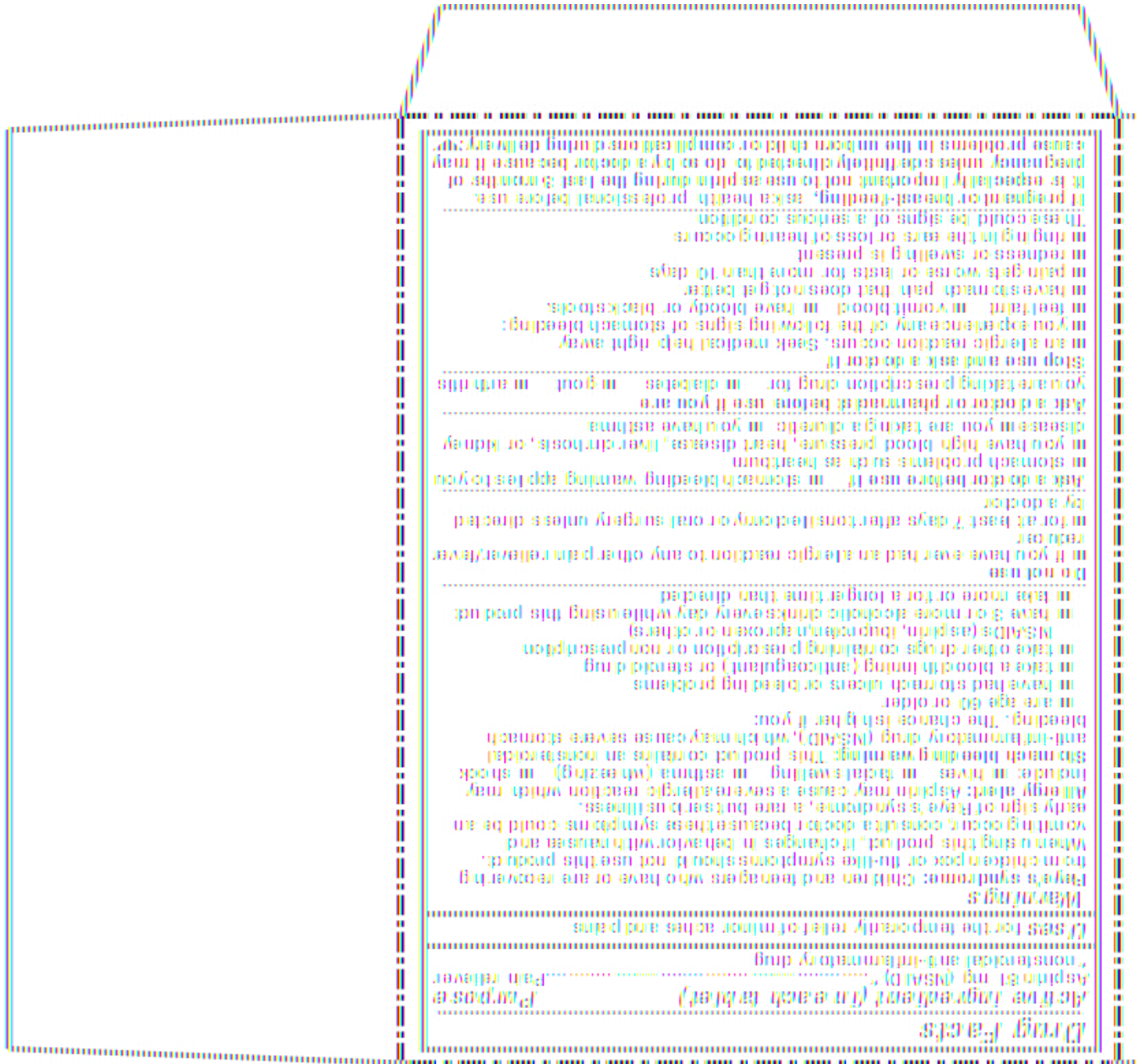
Distributed by:
Raritan Pharmaceuticals
8 Joanna Court,
East Brunswick, NJ 08816

DR CHOICE®

In clinical full glass of water with each dose
in adults and children 12 years and over: take 4-6 tablets every 4 hours
in children under 12 years: consult a doctor
not to exceed 48 tablets in 24 hours unless directed by a doctor
in store at room temperature
Inactive Ingredients: corn starch, dextrose, FD&C yellow #6 aluminum lake, flavors, methocel k100, silica, sucralose

DR CHOICE® is a registered trademark of Raritan Pharmaceuticals, Inc.

ASPIRIN artwork Label Display-2



CHEWABLE ADULT LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-081
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
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	ROUND	Size	8 mm
Flavor	ORANGE	Imprint Code	RP8 1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-081-91	3 in 1 CARTON	06/03/2013	
1		36 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 final	part343	06/03/2013	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 1/2021

Raritan Pharmaceuticals Inc