BIOVANTA TRIP ACTION TART CHERRY AND HONEY- acetylsalicylic acid, menthol lozenge

Applied Biological Laboratories 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.

biovanta Tart Cherry

Drug Facts

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Active Ingredient

Active Ingredient (in each lozenge):

Menthol 5mg.....Antitussive

Acetyl Salicylic Acid* (NSAID)* 6 mg......Analgesic

*nonsteroidal anti-inflammatory drug

Purpose

Antitussive and Analgesic

Uses

- Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants.
- For the temporary relief of minor aches and pains associated with a sore throat.

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:

■ Asthma (wheezing) ■ Hives ■ Facial swelling ■ Shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if the user:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug

- takes other drugs containing prescription or nonprescription NSAIDs (e.g. aspirin, ibuprofen, naproxen, or others)
- takes more than directed or for a longer time than directed
- is age 60 or older
- has 3 or more alcoholic drinks per day while using this product

Ask a doctor before use

Ask a doctor before use if you have:

- a history of stomach problems, such as heartburn
- high blood pressure, heart disease, liver cirrhosis, or kidney disease
- taken a diuretic not been drinking fluids lost a lot of fluid due to vomiting or diarrhea

Stop use

Stop use of this product and ask a healthcare provider if user experiences any of the lollowing signs or stomach bleeding:

■ feels faint ■ vomits blood ■ has bloody or black stools ■ has stomach pain that does not get better

If pregnant or breast-feeding

Pregnancy: If pregnant or breast-feeding, always ask your healthcare provider before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless directed to do so by a doctor as it may cause problems in the unborn child or complications during delivery.

Do not use

Do not use:

- If you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor.
- If allergic to milk and/or egg white, or have ever had an allergic reaction to this product or any of its ingredients.

A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult your healthcare provider.

Keep out of the reach of children

Children Warning: Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- Dissolve1 lozenge slowly in mouth.
- Repeat every 30 minutes as needed or as directed by health care provider.
- Children under 6 consult health care provider.

Other Information

- Store at room temperature.
- Check expiration date before using.
- Tamper Evident: Do not use if tamper seal is broken or missing.
- Do not give lozenges to children younger than age 4.
- Actual lozenge color may vary slightly due to the natural ingredients.

Inactive Ingredients

Aloe, Honey, Isomalt, Lactoferin, Lysozyme, Natural Colors, Natural Cherry Flavor, Sodium Chloride, Stevia Rebaudiana, Water

biovanta Tart Cherry

biovanta™

(NSAID*)

TRIPLE ACTION LOZENGES

- Fights Colds
- Soothes Sore Throats
- Relieves Coughs

Tart Cherry

Non-Drowsy

24 Lozenges

NDC 73678-460-24

Questions or Comments? 866-889-3959

info@appliedbioinc.com

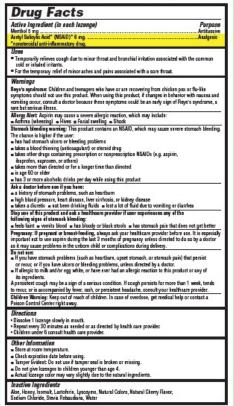
Distributed by:

Applied Biological Laboratories

760 Parkside Ave., 317

Brooklyn, New York 11226







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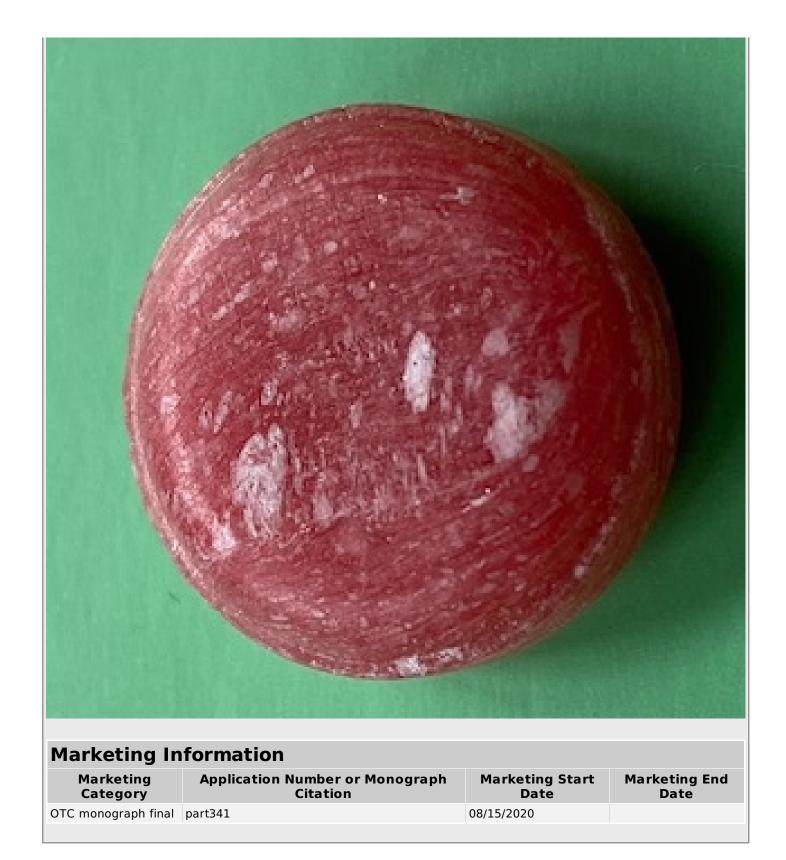
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73678-460	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	6 mg	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg	

Inactive Ingredients				
Ingredient Name	Strength			
ISOMALT (UNII: S870P55O2W)				
HONEY (UNII: Y9H1V576FH)				
LACTOFERRIN, BOVINE (UNII: KG21X1090A)				
LYSOZYME (UNII: 968JKA7T33)				
ALOE (UNII: V5VD430YW9)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
WATER (UNII: 059QF0KO0R)				
STEVIA REBAUDIANA WHOLE (UNII: 6U422Y08O2)				

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	17mm	
Flavor	CHERRY, HONEY	Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73678-460- 24	24 in 1 BOX	08/15/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		



Labeler - Applied Biological Laboratories Inc. (080512733)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lozy's Pharmaceuticals SL.		466116516	manufacture(73678-460)	