BIOVANTA TRIP ACTION LEMON 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 Lemon & Honey

Drug Facts Drug Facts

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:

 \blacksquare Asthma (wheezing) \blacksquare Hives \blacksquare Facial swelling \blacksquare 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

 \blacksquare taken a diuretic \blacksquare not been drinking fluids \blacksquare 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 \blacksquare vomits blood \blacksquare has bloody or black stools \blacksquare has stomach pain that does not get better

Pregnancy: If pregnant or breast-feeding

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 Lemon Flavor, Sodium Chloride, Stevia Rebaudiana, Water

biovanta Lemon & Honey

biovanta™

(NSAID*)

TRIPLE ACTION LOZENGES

- Fights Colds
- Soothes Sore Throats
- Relieves Coughs

Lemon & Honey

Non-Drowsy

24 Lozenges

NDC 73678-360-24

Questions or Comments? 866-889-3959

info@appliedbioinc.com

Distributed by:

Applied Biological Laboratories

760 Parkside Ave. 317

Brooklyn, New York 11226



BIOVANTA TRIP ACTION LEMON AND HONEY acetylsalicylic acid, menthol lozenge								
HUMAN OTC DRUG	Item Code (Source)		NDC:73678-360					
ORAL								
Mojohy								
-			-					
Ingredient Name			gth	Strength				
ASPIRIN (UNII: R16C05Y76E) (ASPIRIN - UNII:R16C05Y76E)				6 mg				
NTHOL - UNII:L7T10EIP3A)		MENTHOL		5 mg				
	HUMAN OTC DRUG ORAL Moiety ient Name	HUMAN OTC DRUG Item Code ORAL Moiety ient Name RIN - UNII:R16CO5Y76E)	HUMAN OTC DRUG Item Code (Source) ORAL Moiety ient Name Basis of Stren RIN - UNII:R16CO5Y76E) ASPIRIN	HUMAN OTC DRUG Item Code (Source) NDC:73 ORAL Moiety ient Name Basis of Strength RIN - UNII:R16CO5Y76E) ASPIRIN				

In	active Ingre	dients				
		Strength				
ISC	OMALT (UNII: S8	70P55O2W)				
нс	ONEY (UNII: Y9H1	V576FH)				
LA	CTOFERRIN, BO	VINE (UNII: KG21X1090A)				
LY	SOZYME (UNII: 9	68JKA7T33)				
AL	OE (UNII: V5VD43	0YW9)				
so	DIUM CHLORID	E (UNII: 451W47IQ8X)				
W	ATER (UNII: 059Q	F0KO0R)				
ST	EVIA REBAUDIA	NA WHOLE (UNII: 6U422Y08O2)				
	roduct Chara	ecteristics yellow	Score		no score	
Sh	ape	· · · · · · · · · · · · · · · · · · ·			17mm	
			Imprint	Code		
Contains						
Pa	ackaging					
#	ltem Code	Package Descript	tion	Marketing Start Date	Marketing End Date	
1	NDC:73678-360- 24	24 in 1 BOX		08/01/2020		
1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product					

1 in 1 BLISTER PACK; Type 0: Not a Combination Product

1 in 1 BLISTER PACK; Type 0: Not a Combination Product

02/01/2023

02/01/2023

2 NDC:73678-360-04 in 1 BOX

3 NDC:73678-360-12 in 1 BOX

04

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Establishment								
Name	Address	ID/FEI	Business Operations					
Lozy's Pharmaceuticals SL.		466116516	manufacture(73678-360)					

Revised: 2/2023

Applied Biological Laboratories Inc.