

OUTGRO- benzocaine liquid
Medtech Products 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.

Outgro

Outgro®

PAIN RELIEVING LIQUID

Drug Facts

Active Ingredient

Benzocaine 20% w/v

Purpose

Topical analgesic

Use

For the temporary relief of pain associated with minor skin irritations.

Warnings

- **For external use only.**
- **Extremely Flammable.** Keep away from fire or flame. Avoid smoking during use and until product has dried.

When using this product:

avoid contact with eyes.

Stop use and ask a doctor if:

- condition worsens
- condition does not improve in 7 days
- condition clears up and occurs again within a few days.

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years of age and older	Using applicator, apply to affected area not more than 3 to 4 times daily
Children under 2 years of age	Consult a doctor

Other Information

- store at room temperature away from heat.

Inactive Ingredients

Alcohol, D&C Yellow #10, FD&C Blue #1, FD&C Red #40, PEG-8

Questions?

1-800-443-4908

Principal Display Panel

Outgro
 BENZOCANE
 PAIN RELIEVING
 LIQUID
 .31 FL OZ / 9 mL

Relieves Foot Pain

■ Temporarily relieves pain and itching of minor skin irritations of toes, heels, arch and ball of foot
 ■ Temporarily relieves pain of skin irritation related to chafing from tight fitting shoes

Outgro
 BENZOCANE

.31 FL OZ / 9mL

With BRUSH APPLICATOR

Outgro PAIN RELIEVING LIQUID

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OUTGRO

benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-531
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	18.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:63029			

1	NDC:55029-531-11	1 in 1 BOX	01/01/2013	
1		9 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC MONOGRAPH NOT FINAL	part348	01/01/2013	

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.