QUALITY CHOICE PAIN RELIEF PATCHES- lidocaine patch
QUALITY CHOICE (Chain Drug Marketing Association)

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.

QUALITY CHOICE PAIN RELIEF PATCHES

Active Ingredients

Lidocaine 4% . . . . . Topical Anesthetic

Purpose

Temporarily relieves minor pain.

Dosage and Administration

Directions Adults and children over 12 years:

■ clean and dry affected area

■ remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle

■ carefully remove smaller portion of backing from patch starting at corner

■ apply sticky side of patch to affected area

■ use one patch for up to 12 hours. **Children under 12 years of age:** consult a physician.

Warnings

For external use only.

Idications and Usage

Uses: Temporaily relieves minor pains.

When using this product

■ use only as directed

■ read and follow all directions and warnings on this carton

■ do not allow contact with the eyes

■ do not use at the same time as other topical analgesics

■ do not bandage tightly or apply local heat (such as heating pads) to the area of use

■ do not microwave

■ dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and consult a doctor

■ condition worsens

■ redness is present

■ irritation develops

■ symptoms persist for more than 7 days or clear up and occur again within a few days

■ you experience signs of skin injury, such as pain, swelling or blistering where the product was applied.

If pregnant or breastfeeding, ask a health professional before use.

Do not Use

■ more than one patch on your body at a time

■ on cut, irritated or swollen skin

■ on puncture wounds

■ for more than one week without consulting a doctor

■ if you are allergic to any active or inactive ingredients

■ if pouch is damaged or opened.

Keep out of reach of children and pets.

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

Other Safety Information

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

Inactive Ingredients

Aluminum Glycinate, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polysorbate 80, Propylene Glycol,
Propylparaben, PVP, Sodium Polyacrylate, Tartaric Acid, Titanium Dioxide, Water

Questions

Customer Care Help Line
248-449-9300
www.qualitychoice.com

Distributed by C.D.M.A., Inc.

43157 W. Nine Mile

Novi, MI 48375

Made in China

QUALITY CHOICE PAIN RELIEF PATCHES

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-309
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM (UNII: CPD4NFA903)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (300000 MW) (UNII: A8371R0U5J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-309-06	5 in 1 CARTON	07/01/2017	
1		9 g in 1 PATCH; 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	07/01/2017	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co.,Ltd.		529128763	manufacture(63868-309)