PURE CBD HYDROGEL XL WITH LIDOCAINE 4%- lidocaine patch
ARI BRANDS, LLC

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.

Pure CBD Hydrogel XL Patch with Lidocaine

PURE CBD HYDROGEL XL PATCH WITH LIDOCAINE – Lidocaine 4% Patch

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Pure CBD Hydrogel XL Patch with Lidocaine 4%

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

Temporarily relieves pain and itching associated with:

• minor burns

• sunburn

• minor cuts

• scrapes

• insect bites

• minor skin irritations

Warnings

For external use only.

Do not use

• More than one patch at a time or on irritated or swollen skin

• On wounds, damaged, or infected skin

• On eyes, mouth, genitals or other mucous membranes

• With a heating pad

• If you are allergic to any ingredients of this product

Allergy Alert: if you are allergic to any inactive ingredient of this product, contact a doctor before use.

When using this product

• Use only as directed. Read and follow all directions and warnings on the carton and packet insert before use.

• **Avoid contact with eyes**, mucous membranes, or rashes.

• Do not bandage tightly or apply local heat (such as heating pads) to the area of use.

• Do not use at the same time as other topical analgesics or anesthetics.

• Dispose of used patch in a 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 physician:

• If pregnant or breast feeding

• If localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling, and blistering

• If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

Keep out of reach of children and pets.

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

Directions

Adults and children 12 years of age and older:

Apply 1 patch to the affected area of intact skin up to 12 hours.

- Clean and dry the affected area.

- Open pouch and remove one patch.

- Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.

- Wash hands with soap and water after handling the patches.

- Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.

- Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

Children under 12 years: Ask a physician

Other information

Store at room temperature 15°-30°C (59°-86°F)

Avoid storing product in direct sunlight and protect product from excessive moisture.

Inactive ingredients

CBD (Hemp Extract), Dihydroxyaluminium Aminoacetate, Disodium Edetate, Gelatin, Glycerin, Kaolin, Methylparaben, Polyacrylic Acid, Polyvinyl Alcohol, Propylene Glycol, Propylparaben, Sodium Carboxymethylcellulose, Sodium Polyacrylate, Sorbitol, Tartaric Acid, Urea and Purified Water.

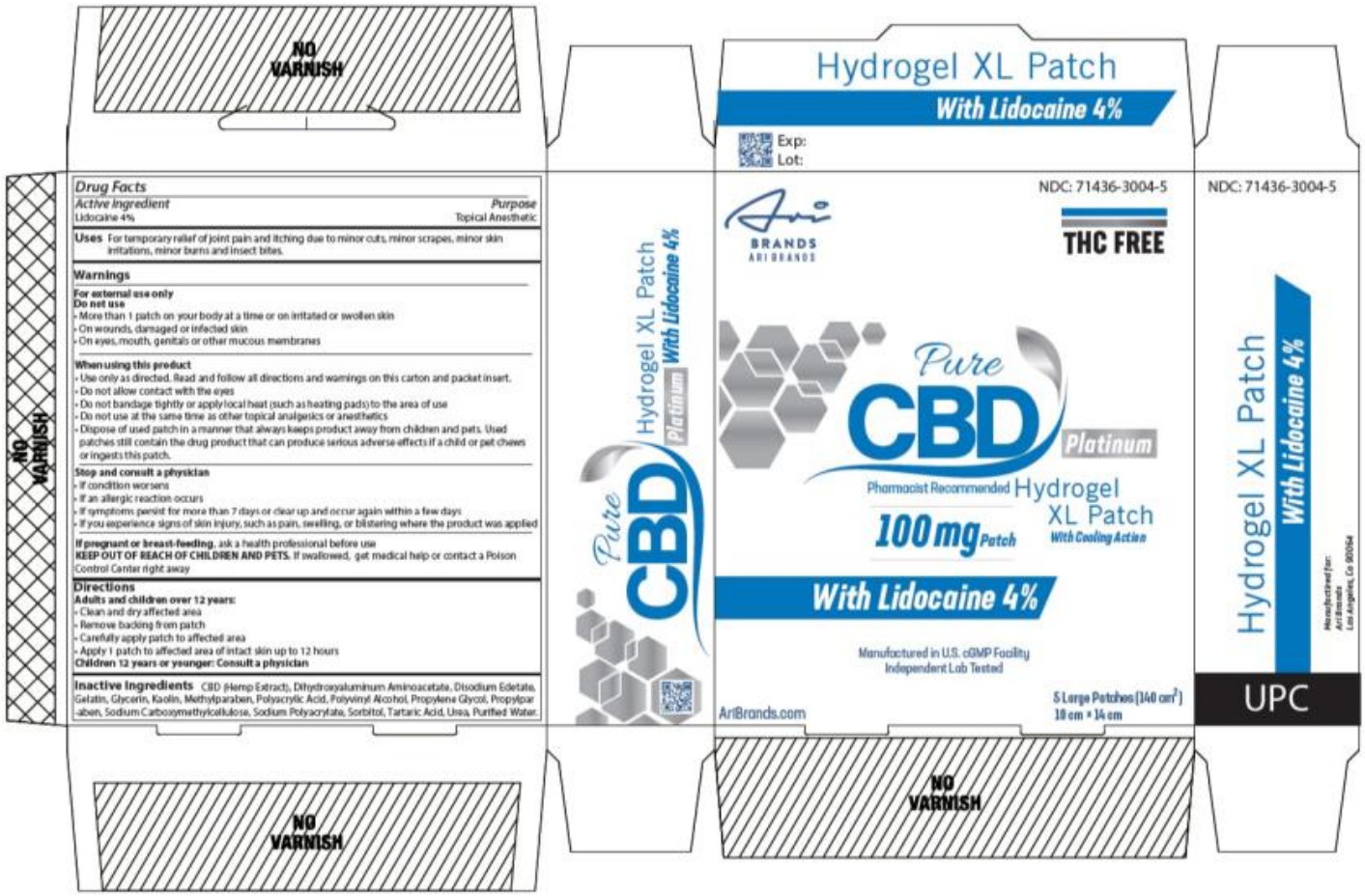
PRINCIPAL DISPLAY PANEL

Pure CBD Hydrogel XL Patch with Lidocaine 4%

NDC 71436-3004-5

5 Patches

Ari Brands, LLC



PURE CBD HYDROGEL XL WITH LIDOCAINE 4%

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71436-3004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
HEMP (UNII: TD1MUT01Q7)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TARTARIC ACID (UNII: W4888I119H)	
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71436-3004-5	5 in 1 CARTON	01/15/2020	
1		15 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	01/15/2020	

Labeler - ARI BRANDS, LLC (080658382)

Establishment

Name	Address	ID/FEI	Business Operations
USpharma Ltd		080664601	MANUFACTURE(71436-3004)

Revised: 1/2020 ARI BRANDS, LLC