

MENTHOREAL-10 KIT- lidocaine/menthol patch

Forreal Pharmaceuticals

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.

MenthoReal-10 Topical Paint Patch Kit

Active ingredients:

Lidocaine HCL 4%

Menthol 4%

Purpose:

Topical Anesthetic

Uses:

For the temporary relief of pain

Warnings:

For external use

Do not use:

- More than 1 patch on your body at a time or on cut, irritated or swollen skin.
- On puncture wounds
- For more than 1 week without consulting a doctor

When using this product:

- Use only as directed. Read and follow all directions and warnings on this label.
- Rare cases of serious burns have been reported with products of this type.
- Do not apply to wounds or damaged, broken or irritated skin.
- Do not allow contact with the eyes and mucous membranes.
- 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.
- 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 ask a doctor if:

- 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 breast-feeding, ask a health care professional before use.

Keep out of reach of children and pets.

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

Directions:

Adults and children over 12 years:

- Clean and dry the affected area.
- Open pouch and remove one patch.
- Remove the protective film from the patch and apply patch to the affected area.
- Reseal pouch containing unused patches after each use.
- Use 1 patch for up to 12 hours.

Children 12 years or younger:

- Ask a doctor

Other Information:

- Avoid storing product in direct sunlight
- Protect product from excessive moisture

Other Ingredients:

Acrylic Adhesive

Questions or comments? 877-367-3250

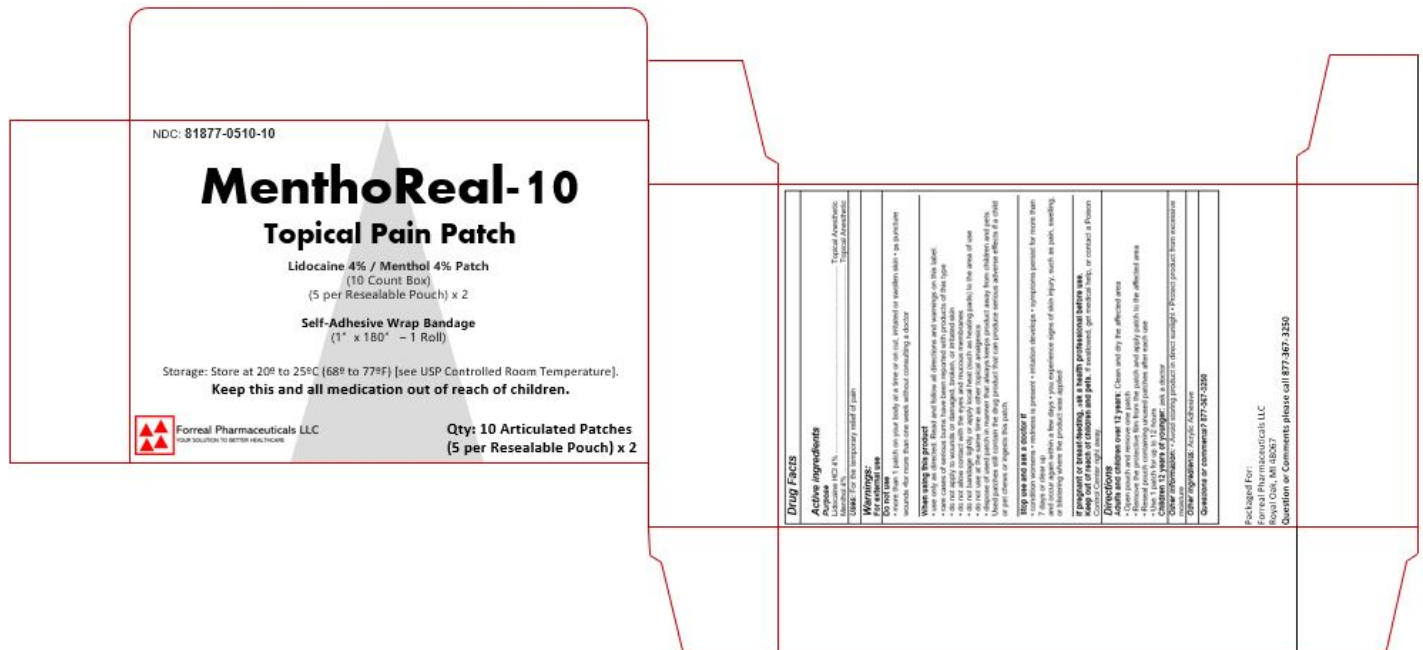
Packaged For:

Forreal Pharmaceuticals LLC

Royal Oak, MI 48067

NDC: 81877-510-10

QTY: 10 Articulated patches (5 per Resealable Pouch) x 2



MENTHOREAL-10 KIT

lidocaine/menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81877-510(NDC:70512-013)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	40 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	

Product Characteristics

Color		Score	
Shape	RECTANGLE (White flexible patch)	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81877-510-10	2 in 1 BOX	02/01/2021	
1		1 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/01/2021	

Labeler - Forreal Pharmaceuticals (118029197)

Revised: 10/2021

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