

## **IMBUE PAIN RELIEF- menthol - methyl salicylate patch**

**Imbue Body 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.*

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### **Drug Facts**

#### **Active Ingredients**

Menthol 51 mg / patch

Methyl Salicylate 15 mg / patch

#### **Purpose**

Topical Analgesic

Topical Analgesic

**Uses:** Temporarily relieves minor aches and pains of muscles and joints associated with:

• simple backache • muscle strain • sprains • arthritis • bruises • bursitis • tendinitis.

**Warnings** FOR EXTERNAL USE ONLY

#### **When using this product:**

- Use only as directed
- Do not get into eyes or on mucus membranes
- Do not apply to wounds, damaged or irritated skin
- Do not bandage tightly or use with a heating pad

#### **Stop use and ask a doctor if:**

- Condition worsens
- Severe skin irritation develops
- Pain persists for more than 7 days

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Adults and children over 12 years:

- Peel clear film off carefully. Avoid letting the sticky surface of the patch adhere to itself.
- Place sticky surface of patch on skin, covering as much of the painful area as possible.
- Leave in place for up to 8 hours. Pain relief is occasionally delayed.
- Use 1 - 2 patches per day. Wait 12 - 24 hours before applying additional patches, to avoid skin irritation.
- Wash hands after applying patch.
- If patch is difficult to remove from skin, soak in warm water or vegetable oil, then peel off slowly.

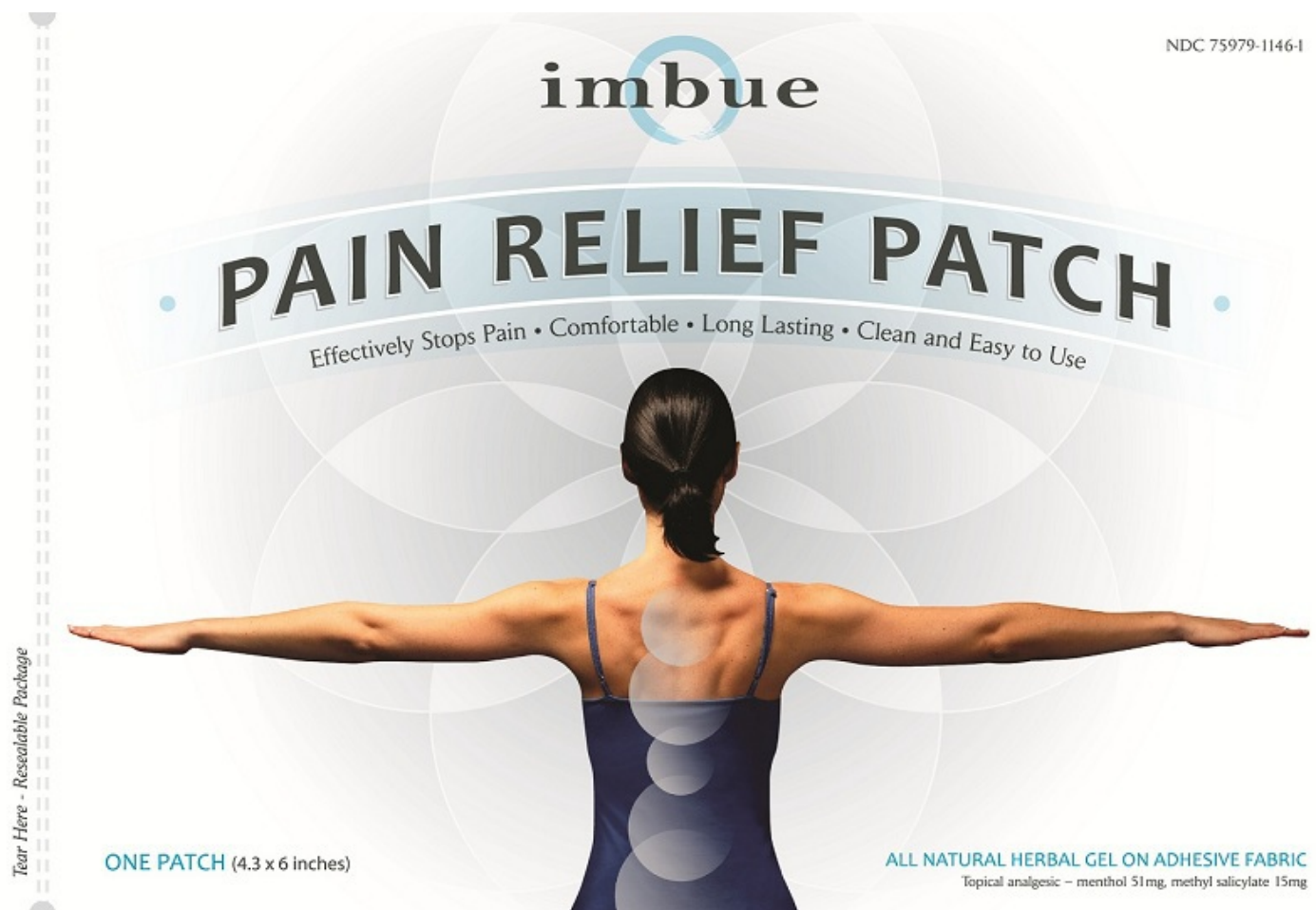
- Patch may be cut to size (before removing protective film) to treat smaller areas.
- See Additional Tips for more helpful information.

Children 12 years or younger: ask a doctor before use.

### Other Information

- This product may cause skin rash in some individuals.
- Store in a cool area away from direct sunlight.
- Always re-seal pouch containing unused patches.

**Inactive Ingredients:** *Acorus gramineus* rhizome, *Angelica sinensis* root, *Artemisia argyi* leaf, *Atractylodes lancea* rhizome, black sesame oil, *Boswellia carterii* resin, *Carthamus tinctorius* flower, *Cinnamomum verum* bark, *Cnidium monnieri* fruit, *Commiphora myrrha* resin, *Cyathula officinalis* root, *Cymbopogon citratus* essential oil, *Dioscorea hypoglauca* rhizome, *Drynaria fortunei* rhizome, *Eletherococcus nodiflorus* root cortex, *Ephemerantha fimbriata* aerial parts, *Gentiana macrophylla* root, *Helichrysum italicum* essential oil, *Lavandula angustifolia* essential oil, *Ligusticum chuanxiong* root, *Paeonia lactiflora* root, *Pinellia ternata* rhizome, *Pinus massoniana* resin, *Saussurea lappa* root, zinc oxide.



Drug Facts	
Active Ingredients	Purpose
Menthol 51mg/patch	Topical analgesic
Methyl Salicylate [from oil of wintergreen] 15mg/patch	Topical analgesic
<b>Uses</b> Temporarily relieves minor aches and pains of muscles and joints associated with: • simple backache • muscle strain • sprains • arthritis • bruises • bursitis • tendinitis	
<b>Warnings</b> FOR EXTERNAL USE ONLY	
<b>When using this product:</b> • Use only as directed • Do not get into eyes or on mucous membranes • Do not apply to wounds, damaged or irritated skin • Do not bandage tightly or use with a heating pad	
<b>Stop use and ask a doctor if:</b> • Condition worsens • Severe skin irritation develops • Pain persists for more than 7 days	
<b>If pregnant or breast-feeding,</b> ask a health care professional before use.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b> Adults and children over 12 years: • Peel clear film off carefully. Avoid letting the sticky surface of the patch adhere to itself. • Place sticky surface of patch on skin, covering as much of the painful area as possible. • Leave in place for up to 8 hours. Pain relief is occasionally delayed. • Use 1 - 2 patches per day. Wait 12 - 24 hours before applying additional patches, to avoid skin irritation. • Wash hands after applying patch. • If patch is difficult to remove from skin, soak in warm water or vegetable oil, then peel off slowly. • Patch may be cut to size (before removing protective film) to treat smaller areas. • See Additional Tips for more helpful information. Children 12 years or younger: ask a doctor before use.	
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## PAIN RELIEF PATCH

Get Back to Doing What You Love

Use wherever pain occurs

**ADDITIONAL TIPS FOR USE**

- If you have difficulty keeping the Imbue Patch from sticking to itself before applying it, try this: Peel off 1-2 inches of the clear film from one end. Place the exposed sticky surface on the skin, then peel the remainder of the backing off from underneath while pressing the patch onto the skin.
- If you have sensitive skin, you may wish to perform a patch test to make sure your skin will not react to this product. Cut a postage stamp-sized piece from the Imbue Patch and place it on the inside of the wrist or underside of the arm. Wear the patch for 8 hours. If irritation occurs, the Imbue Patch may not be suitable for you.
- If the patch begins to peel off before you are ready to remove it, you may use medical tape to keep it on.
- You may cut slits in the patch to fit flexible locations like knees and elbows.

**FOR MORE IDEAS AND EXPERT ADVICE ON RELIEVING YOUR PAIN, PLEASE VISIT US ONLINE AT [www.imbuebody.com](http://www.imbuebody.com)**

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Manufactured by

3 Mast Pharmaceutical Co.  
Tainan, Taiwan

7 38435 20097 8

Lot #

Exp:

## IMBUE PAIN RELIEF

menthol - methyl salicylate patch

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:759 79-1146
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	51 mg
Methyl salicylate (UNII: LAV5U5022Y) (salicylic acid - UNII:O414PZ4LPZ)	Methyl salicylate	15 mg

### Inactive Ingredients

Ingredient Name	Strength
Acorus gramineus root (UNII: Z60N6Q6E19)	

<b>Angelica sinensis root</b> (UNII: B66F4574UG)	
<b>Artemisia argyi leaf</b> (UNII: 2JYC99Q0WZ)	
<b>Atractylodes lancea root</b> (UNII: CAZ6282J2O)	
<b>Sesame oil</b> (UNII: QX10HYY4QV)	
<b>Frankincense</b> (UNII: R9XLF1R1WM)	
<b>Safflower</b> (UNII: 4VBL71TY4Y)	
<b>Cinnamon</b> (UNII: 5S29HWU6QB)	
<b>Cnidium monnieri fruit</b> (UNII: V1IA3S3CUS)	
<b>Myrrh</b> (UNII: JC71GJ1F3L)	
<b>Cyathula officinalis root</b> (UNII: BRM37UP34O)	
<b>West Indian lemongrass oil</b> (UNII: 5BIA40E9ED)	
<b>HELICHRYSUM ITALICUM FLOWER OIL</b> (UNII: O97ZV7726K)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>LIGUSTICUM SINENSE SUBSP. CHUANXIONG ROOT</b> (UNII: RR83T99U97)	
<b>PAEONIA LACTIFLORA ROOT</b> (UNII: 3Z3866YW6P)	
<b>SAUSSUREA COSTUS ROOT</b> (UNII: RUP970CGR9)	
<b>Zinc oxide</b> (UNII: SOI2LOH54Z)	
<b>Dioscorea collettii var. hypoglauca root</b> (UNII: N57RVD5L6U)	
<b>Drynaria fortunei root</b> (UNII: 731W842X8Q)	
<b>Flickingeria fimbriata stem</b> (UNII: D6E4A8IAEP)	
<b>Gentiana macrophylla root</b> (UNII: 6559FC0U1B)	
<b>PINELLIA TERNATA ROOT</b> (UNII: G9AET085M5)	
<b>Pinus massoniana resin</b> (UNII: 64S07U83T7)	
<b>Rosin</b> (UNII: 88S87KL877)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75979-1146-1	1 in 1 POUCH		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/01/2011	

### Labeler - Imbue Body LLC (965843878)

### Establishment

Name	Address	ID/FEI	Business Operations
Taiwan Three Mast Pharmaceutical Company		658305156	manufacture