CHI-MYST SYNERGY TOPICAL- chitosan ketorolac bupivacaine lidocaine suspension spray, metered
Prescription Care LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Chi-Myst Synergy Topical

Drug Information

Warnings and Precautions
For EXTERNAL use only. AVOID eye contact.
Discontinue Chi-Myst and consult with your physician:
• If your condition worsens
• If your symptoms do not improve after 10 days, unless directed by a physician
• If a rash appears, or reaction to the medication is experienced at the point of application
Chi-Myst includes a chitin derivative, which is produced from shrimp shells. While it is unlikely to affect those suffering from shrimp or shellfish allergies, patients with allergies to shrimp or other shellfish should ask their physician before using Chi-Myst.

Indications/Uses:
Anti-inflammatory (osteoarthritis, tendonitis, joint or musculoskeletal pain)

How To Take This Medication:
Adults and children 2 years of age or older SPRAY onto affected area or spray into palm and lightly apply to tender area. Dosage is determined by your physician, and will vary by intensity of pain, as well as the nature, size and location of the affected area. Chi-Myst may be used as often as once every three hours to combat fierce pain and inflammation, or more often if prescribed by your doctor. Use only as directed. Only use the prescribed number of sprays per application, as multiple sprays have not been shown to be any more effective than one or two sprays to the affected area. Most patients prefer to spray Chi-Myst directly on the affected area. It is not recommended to rub-in Chi-Myst, as the transdermal agent absorbs efficiently and naturally through the skin. For particularly tender or isolated areas, and open wounds, it is recommended to spray Chi-Myst on clean fingertips, and gently distribute the medication to the affected area. Allow Chi-Myst to absorb before allowing the treated area to come in contact with clothing or furniture.

Side Effects:
Due to the unique transdermal delivery method of the active ingredients, no side effects have been observed. However, physicians should instruct patients to report any unusual local side effects to the prescriber.

Drug Interactions:
Chi-Myst includes a chitin derivative, which is produced from shrimp shells. While it is unlikely to affect those suffering from shrimp or shellfish allergies, patients with allergies to shrimp or other shellfish should ask their physician before using Chi-Myst.

Storage/Handling:
Chi-Myst should be stored in a room-temperature environment (between 65F and 79F), and not exposed to direct sunlight for long periods of time.

Inactive Ingredients:
glycerin, a proprietary glucosamine polymer, lactic acid, sodium hydroxide

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chitosan ketorolac bupivacaine lidocaine suspension spray, metered

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70486-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BUPIVACAINE HYDROCHLORIDE (UNII: 7TQO7W3VT8) (BUPIVACAINE - UNII:Y8335394RO)	BUPIVACAINE HYDROCHLORIDE ANHYDROUS	0.09 g in 30 mL
KETOROLAC TROMETHAMINE (UNII: 4EVE5946BQ) (KETOROLAC - UNII:YZI5105V0L)	KETOROLAC	0.45 g in 30 mL
CHITOSAN LOW MOLECULAR WEIGHT (20-200 MPA.S) (UNII: SBD1A2I75N) (CHITOSAN LOW MOLECULAR WEIGHT (20-200 MPA.S) - UNII:SBD1A2I75N)	CHITOSAN LOW MOLECULAR WEIGHT (20-200 MPA.S)	0.03 g in 30 mL
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	1.5 g in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 30 mL
WATER (UNII: 059QF0KO0R)	30 mL in 30 mL
LACTIC ACID LACTATE, DL- (UNII: N37QW3EK1L)	0.042 mL in 30 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.01950 g in 30 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70486-030-00	30 mL in 1 BOTTLE, SPRAY; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2016	

Labeler - Prescription Care LLC (080059076)

Registrant - Prescription Care LLC (080059076)

Establishment

Name	Address	ID/FEI	Business Operations
Prescription Care LLC		080059076	manufacture(70486-030)