TRIFENA- diclofenac sodium, lidocaine, and menthol, (plus)minus patch
Trifluent Pharma LLC

Trifena™

Drug Facts

Active Ingredients	
Diclofenac Sodium, USP 1.2%	Arthritis Pain Reliever
Menthol, USP 5%	Topical Analgesic
Lidocaine, USP 4%	Topical Anesthetic

Uses

For the temporary relief of pain.

Warnings

For External Use Only. Topical use only

Allergy Alert

Diclofenac may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- Hives
- Asthma (wheezing)
- Skin Reddening
- Blisters
- Facial Swelling
- Shock
- Rash.

If an allergic reaction occurs, stop use and see medical attention immediately.

Liver Warning

This product contains Diclofenac. Liver damage may occur if you apply

- more or for a longer time than directed or
- when using other drugs containing Diclofenac.

Stomach Bleeding Warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is small, but higher if you:

- Are age 60 or older
- Have had stomach ulcers or bleeding problems
- Taking a blood thinning (anticoagulant) or steroid drug

- Taking other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen or others)
- Having 3 or more alcoholic drinks every day.
- Applying more or for longer than directed.

Do Not Use

- On damaged, irritated or infected skin
- With a bandage or eating pad
- If you are allergic to any ingredients in this product
- Right before or after heart surgery
- In the eyes, nose or mouth
- Otherwise than directed.

When Using This Product

Avoid contact with the eyes or mucous membranes

Stop Use and Ask a Doctor If

- Any of the Warnings apply to you
- You are taking a diurectic
- You are taking any other drugs
- You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- Excessive skin irritation develops
- Condition worsens
- Symptoms persist for more than 7 days, or symptoms clear up and occur again within 3 days

If Pregnant or Breast-Feeding

Ask a health professional before use.

It is especially important not to use Diclofenac at 20 weeks or later in pregnancy, unless directed by a doctor to do so.

Keep Out of Reach of Children

If ingested seek medical help or contact a Poison Control Center immediately

Flammable

Keep away from excessive heat or open flame

Directions

Adults and Children 12 Years of Age and Older:

- Clean and dry to affected area
- Apply gel pad directly to your skin for up to 12 hours
- Using both hands remove the release film from one corner and apply the gel patch adhesive side to the skin affected area.
- Gel pad can be cut into pieces and used on up to 2 body parts at a time

- One application per day is recommended
- Wash hands immediately after use.

Other Information

- Store at 59°F - 77°F with seal tightly sealed.
- If the tamper-evident foil seal is not intact, do not use

Inactive Ingredients

Alpha Tocopherol Acetate, Aluminum Glycinate, Aluminium Hydroxide, Borax, Carbomer, Collodial Silicon Dioxide, DMDM Hydantion, Glycerine, Polyacrylic Acid, Polyvinyl Alcohol, Polyvinylpyrrolidone, Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Ethylenediaminetetraacetic Acid, Sodium Polyacrylate, Sorbitan Monooleate, Tartaric Acid & Titanium Dioxide.

Questions or Comments?

1-210-944-6920

PRINCIPAL DISPLAY PANEL - 15 Patch Carton

NDC 73352-565-01

15 PATCHES

trifena™

Pain Relief Patch

Diclofenac Sodium, USP 1.2%
Menthol, USP 5%
Lidocaine, USP 4%

TRIFLUENT
PHARMA®

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● On damaged, irritated, or infected skin ● With a bandage or heating pad ● If you are allergic to any ingredients in this product ● Right before or after heart surgery ● In the eyes, nose, or mouth ● Otherwise as directed.

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Questions or Comments? 1-210-944-6920

Manufactured For:
Trifluent Pharma LLC
San Antonio, TX 78213
Website: www.trifenapatches.com

Made in India
Neutral Code: HP/Drugs/MNB/06/348

trifena™

TRIFENA

diclofenac sodium, lidocaine, and menthol, (plus)minus patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73352-565
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DICLOFENAC SODIUM (UNII: QTG126297Q) (DICLOFENAC - UNII:144O8QL0L1)	DICLOFENAC SODIUM	0.012 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g
MENTHOL, (+)- (UNII: C6B1OE8P3W) (MENTHOL, (+)- - UNII:C6B1OE8P3W)	MENTHOL, (+)-	0.05 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K90 (UNII: RDH86HJV5Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73352-565-01	15 in 1 CARTON; Type 0: Not a Combination Product	11/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/01/2023	

Labeler - Trifluent Pharma LLC (117167281)

Revised: 11/2023 Trifluent Pharma LLC