

**FAMILY CARE THERA FLEX- menthol glycol salicylate nonivamide tocopherol acetate patch
United Exchange Corp.**

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.

| Active Ingredients (in each patch) | Purpose |
|------------------------------------|-------------------|
| Menthol 6.53%..... | Topical analgesic |
| Glycol Salicylate 4.66%..... | Topical analgesic |
| Nonivamide 0.01%..... | Topical analgesic |
| Tocopherol Acetate 0.93%..... | Topical analgesic |

Uses: Temporarily relieves mild to moderate aches & pain of muscles & joints associated with:

- strains
- sprains
- simple backache
- arthritis
- bruises

For external use only

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

- are 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing an NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using the product
- take more or for a longer time than directed

Do not use:

- on the face or rashes
- on wounds or damaged skin
- if allergic to aspirin or other NSAIDs
- with a heating pad
- when sweating (such as from exercise or heat)
- any patch from a pouch that has been open for 14 or more days
- right before or after heart surgery

Ask a doctor before use:

- if you are allergic to topical products
- the stomach bleeding warning applies to you
- you have high blood pressure, heart disease, or kidney disease
- you are taking a diuretic

When using this product

- wash hands after applying or removing patch. Avoid contact with eyes. If eye contact occurs, rinse thoroughly with water
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if:

- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding
- rash, itching or skin irritation develops
- conditions worsens
- symptoms last for more than 3 days
- symptoms clear up and occur again within a few days
- stomach pain or upset gets worse or lasts

If pregnant or breast-feeding, ask a doctor before use while breast-feeding or during the first 6 months of pregnancy. Do not use during the last 3 months of pregnancy because it may cause problems in the unborn child or complications during delivery.

If put in mouth, get medical help or contact a Poison Control Center right away. Package not child resistant.

Directions: Adult 18 years and older

- clean and dry affected area
- remove patch from backing film and apply to skin (see illustration)
- apply one patch to the affected area and leave in place for up to 8 to 12 hours
- if pains last after using the first patch, a second patch may be applied for up to another 8 to 12 hours
- only use one patch at a time
- do not use more than 2 patches per day
- do not use for more than 3 days in a row
- Children under 18 years of age: do not use

Other Information

- some individuals may not experience pain relief until several hours after applying the patch
- avoid storing product in direct sunlight
- protect product from excessive moisture
- store at 20°-25°C (68°-77°F)

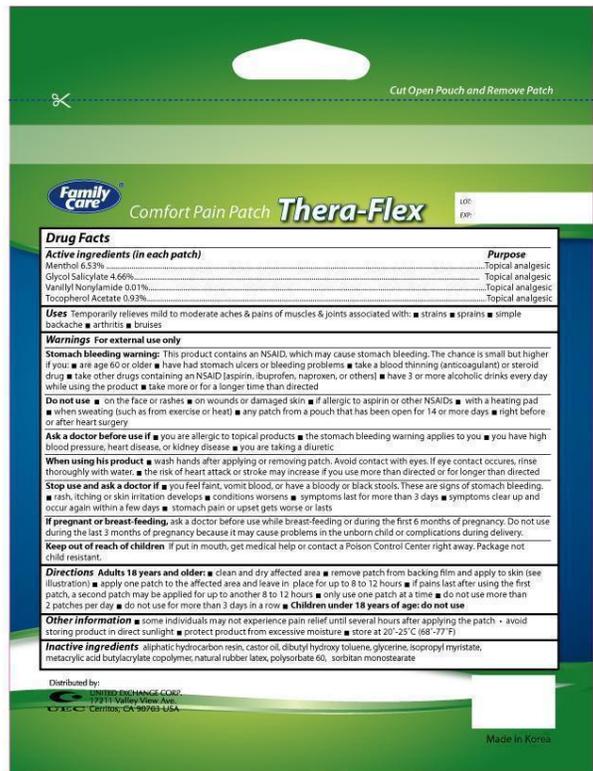
Inactive ingredients: aliphatic hydrocarbon resin, castor oil, dibutyl hydroxy toluene, glycerine, isopropyl myristate, metacrylic acid butylacrylate copolymer, natural rubber latex, polysorbate 60, sorbitan monostearate

DISTRIBUTED BY:

UNITED EXCHANGE CORP.

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CERRITOS, CA 90703 USA



FAMILY CARE THERA FLEX

menthol glycol salicylate nonivamide tocopherol acetate patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65923-012 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 6.53 mg in 100 mg |
| GLYCOL SALICYLATE (UNII: 311VBB7AXH) (GLYCOL SALICYLATE - UNII:311VBB7AXH) | GLYCOL SALICYLATE | 4.66 mg in 100 mg |
| NONIVAMIDE (UNII: S846B891OR) (NONIVAMIDE - UNII:S846B891OR) | NONIVAMIDE | .01 mg in 100 mg |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1) | ALPHA-TOCOPHEROL ACETATE | .93 mg in 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------|----------|
| CASTOR OIL (UNII: D5340Y2I9G) | |

| | |
|--|--|
| GLYCERIN (UNII: PDC6A3C00X) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| NATURAL LATEX RUBBER (UNII: 2LQ0UUW8IN) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:65923-012-01 | 1 in 1 POUCH | | |
| 1 | | 1 mg in 1 PATCH | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 11/15/2013 | |

Labeler - United Exchange Corp. (840130579)

Revised: 11/2013

United Exchange Corp.