TRAULEVIUM- arnica montana radix, calendula officinalis, hamamelis virginiana, echinacea, echinacea purpurea, chamomilla, symphytum officinale, bellis perennis, hypericum perforatum, millefolium, aconitum napellus, belladonna, mercurius solubilis, hepar sulphuris calcareum. ointment
Medical Technology Products, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Traulevium Pain Relief Ointment

ACTIVE INGREDIENTS

Active ingredients (HPUS*)	***Purpose****
Each 50 g of ointment contains:	
Arnica Montana, Radix 3X 750 mg	Reduces joint & back pain
Calendula Officinalis MT (N) 225 mg	Relieves pain
Hamamelis Virginiana MT (N) 225 mg	Relieves joint & muscle soreness
Echinacea MT (N) 75 mg	Relieves pain
Echinacea Purpurea MT (N) 75 mg	Relieves pain
Chamomilla MT (N) 75 mg	Soothing pain relief
Symphytum Officinale 4X (Final concentration 6X) 50 mg	Relieves joint pain
Bellis Perennis MT (M) 50 mg	Relieves joint & muscle soreness
Hypericum Perforatum 6X 45 mg	Relieves pain
Millefolium MT (N) 45 mg	Relieves pain
Aconitum Napellus 1X (Final concentration 4X) 25 mg	Reduces joint & back pain
Belladonna 1X 25 mg	Reduces back pain
Mercurius Solubilis 6X 20 mg	Reduces joint & back pain
Hepar Sulphuris Calcareum 6X 12.5 mg	Relieves pain

USES

Uses* For the temporary relief of:

- Joint Pain
- Back Pain
- Muscular Pain

WARNINGS

Warnings

For external use only.

- Do not apply over open wounds or broken skin.
- If symptoms worsen or persist for more than a week, or if a rash develops, a healthcare provider should be consulted.
- In rare cases, allergic skin reactions may develop.
- **Do not use** if known sensitivity to Traulevium or any of its ingredients exists.
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.
- **If pregnant or breast-feeding,** consult a healthcare provider before use.
- **Contraindications:** Known allergy (hypersensitivity) to one of the ingredients, including plants of the daisy family (Asteraceae) such as Arnica montana (arnica), Calendula officinalis (pot marigold), Chamomilla (German chamomile), Echinacea (coneflower), Achillea millefolium (yarrow), Bellis perennis (daisy) and emulsifying cetylstearyl alcohol.

Keep out of the reach of children.

DIRECTIONS

Adults and children 4 years and older	Apply generously to affected areas 2 to 3 times daily, or more often if necessary. Massage thoroughly into the skin. If appropriate, mild compression or occlusive bandaging may be applied.
Children under 4	Consult your healthcare provider.

OTHER INFORMATION

Other information

Tamper evident: Do not use if protective seal under cap is broken. Store at room temperature. Protect from light. Please retain outer carton for full product instructions.

***These statements have not been reviewed by the Food and Drug Administration. They are supported by traditional homeopathic principles.*

**The letters 'HPUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopeia of the United States.*

INACTIVE INGREDIENTS

Inactive ingredients:

Cetylstearyl alcohol, ethanol, paraffin, purified water and white petrolatum.

QUESTIONS?

Questions?

Call 1.866.440.7703 or e-mail info@traulevium.com

Made in the USA.

Manufactured exclusively for Medical Technology Products, Inc. by OHM pharma Inc.

Medical Technology Products, Inc.

Riviera Beach, FL 33407, USA.

www.traulevium.com

PACKAGE LABELING

NDC 70857-001-50

Traulevium ™

Pain Relief Ointment

Homeopathic Medicine

Compare to Traumeel®. Traumeel is a brand name owned by Biologische Heilmittel Heel GmbH. Traulevium is not associated with the brand owner.

Net Wt. 1.76 oz (50 g)

Pain Relief Ointment

TRAULEVIUM

arnica montana radix, calendula officinalis, hamamelis virginiana, echinacea, echinacea purpurea, chamomilla, symphytum officinale, bellis perennis, hypericum perforatum, millefolium, aconitum napellus, belladonna, mercurius solubilis, hepar sulphuris calcareum. ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70857-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)	ARNICA MONTANA ROOT	3 [hp_X] in 50 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	225 mg in 50 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	225 mg in 50 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	75 mg in 50 g
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	75 mg in 50 g
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	75 mg in 50 g

COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 50 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	50 mg in 50 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 50 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6SW4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6SW4PK)	ACHILLEA MILLEFOLIUM	45 mg in 50 g
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	4 [hp_X] in 50 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	1 [hp_X] in 50 g
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 50 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70857-001-50	1 in 1 BOX	10/12/2016	
1		50 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		10/12/2016	

Labeler - Medical Technology Products, Inc. (150890841)

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