

TRAULEVIUM PAIN RELIEF GEL- arnica montana, calendula officinalis, hamamelis virginiana, echinacea, echinacea purpurea, chamomilla, symphytum officinale, bellis perennis, hypericum perforatum, millefolium, aconitum napellus, belladonna, mercurius solubilis, hepar sulphuris calcareum. gel 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 Gel

ACTIVE INGREDIENTS

Active ingredients (HPUS*)	Purpose**
Each 100 g of gel contains:	
Arnica Montana, Radix 3X 1500 mg	Reduces joint & back pain
Calendula Officinalis MT (N) 450 mg	Relieves pain
Hamamelis Virginiana MT (N) 450 mg	Relieves joint & muscle soreness
Echinacea MT (N) 150 mg	Relieves pain
Echinacea Purpurea MT (N) 150 mg	Relieves pain
Chamomilla MT (N) 150 mg	Soothing pain relief
Symphytum Officinale 4X (Final concentration 6X) 100 mg	Relieves joint pain
Bellis Perennis MT (M) 100 mg	Relieves joint & muscle soreness
Hypericum Perforatum 6X 90 mg	Relieves pain
Millefolium MT (N) 90 mg	Relieves pain
Aconitum Napellus 1X (Final concentration 4X) 50 mg	Reduces joint & back pain
Belladonna 1X 50 mg	Reduces back pain
Mercurius Solubilis 6X 40 mg	Reduces joint & back pain
Hepar Sulphuris Calcareum 6X 25 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.

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 around the pump is broken or missing. Store at room temperature. Protect from light.

***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:

Carbopol 980, ethanol, purified water and sodium hydroxide.

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

NDC 70857-004-16

Traulevium™

Pain Relief Gel

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. 16oz (454 g)

<p>Drug Facts (continued)</p> <p>Other information Tamper evident: Do not use if protective seal around the pump is broken or missing. Store at room temperature. Protect from light. *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.</p> <p>Inactive ingredients Carbopol 980, ethanol, purified water and sodium hydroxide.</p> <p>Questions? Call 1.866.440.7703 or email info@traulevium.com</p> <p>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</p> 	<p>NDC 70857-004-16</p> <p>Traulevium™ PAIN RELIEF GEL</p> <p>Homeopathic Medicine</p> <p><i>Compare to Traumeel®. Traumeel is a brand name owned by Biologische Heilmittel Heel GmbH. Traulevium is not associated with the brand owner.</i></p> <p>Net Wt. 16 oz (454 g)</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredients (HPUS*)</th><th>Purpose¹</th></tr></thead><tbody><tr><td colspan="2">Each 100 g of gel contains:</td></tr><tr><td>Arnica Montana, Rectx 3X 1500 mg</td><td>Reduces joint & back pain</td></tr><tr><td>Calendula Officinalis MT (N) 450 mg</td><td>Relieves pain</td></tr><tr><td>Hamamelis Virginiana MT (N) 450 mg</td><td>Relieves joint & muscle soreness</td></tr><tr><td>Echinacea MT (N) 150 mg</td><td>Relieves pain</td></tr><tr><td>Echinacea Purpurea MT (N) 150 mg</td><td>Relieves pain</td></tr><tr><td>Chamomilla MT (N) 150 mg</td><td>Soothing pain relief</td></tr><tr><td>Symphytum Officinale 4X (Final concentration 6X) 100 mg</td><td>Relieves joint pain</td></tr><tr><td>Bellis Perennis MT (M) 100 mg</td><td>Relieves joint & muscle soreness</td></tr><tr><td>Hypericum Perforatum 6X 90 mg</td><td>Relieves pain</td></tr><tr><td>Millefolium MT (N) 90 mg</td><td>Relieves pain</td></tr><tr><td>Aconitum Napellus 1X (Final concentration 4X) 50 mg</td><td>Reduces joint & back pain</td></tr><tr><td>Belladonna 1X 50 mg</td><td>Reduces back pain</td></tr><tr><td>Mercurius Solubilis 6X 40 mg</td><td>Reduces joint & back pain</td></tr><tr><td>Hepar Sulphuris Calcareum 6X 25 mg</td><td>Relieves pain</td></tr></tbody></table> <p>Uses¹ For the temporary relief of: ■ Joint Pain ■ Back Pain ■ Muscular Pain</p> <p>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, ask a healthcare provider before use.</p> <p>Directions 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.</p> <p>Adults and children 4 years and older Children under 4 Consult your healthcare provider.</p>	Active ingredients (HPUS*)	Purpose ¹	Each 100 g of gel contains:		Arnica Montana, Rectx 3X 1500 mg	Reduces joint & back pain	Calendula Officinalis MT (N) 450 mg	Relieves pain	Hamamelis Virginiana MT (N) 450 mg	Relieves joint & muscle soreness	Echinacea MT (N) 150 mg	Relieves pain	Echinacea Purpurea MT (N) 150 mg	Relieves pain	Chamomilla MT (N) 150 mg	Soothing pain relief	Symphytum Officinale 4X (Final concentration 6X) 100 mg	Relieves joint pain	Bellis Perennis MT (M) 100 mg	Relieves joint & muscle soreness	Hypericum Perforatum 6X 90 mg	Relieves pain	Millefolium MT (N) 90 mg	Relieves pain	Aconitum Napellus 1X (Final concentration 4X) 50 mg	Reduces joint & back pain	Belladonna 1X 50 mg	Reduces back pain	Mercurius Solubilis 6X 40 mg	Reduces joint & back pain	Hepar Sulphuris Calcareum 6X 25 mg	Relieves pain
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Pain Relief Gel

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70857-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	3 [hp_X] in 100 g
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	0.45 g in 100 g
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	0.45 g in 100 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	0.15 g in 100 g
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	0.15 g in 100 g
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	0.15 g in 100 g
COMFREY ROOT (UNII: M9VVZ08EKQ) (COMFREY ROOT - UNII:M9VVZ08EKQ)	COMFREY ROOT	6 [hp_X] in 100 g
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	0.1 g in 100 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 100 g
ACHILLEA MILLEFOLIUM (UNII: 2FXJ6S W4PK) (ACHILLEA MILLEFOLIUM - UNII:2FXJ6S W4PK)	ACHILLEA MILLEFOLIUM	0.09 g in 100 g
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	4 [hp_X] in 100 g
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	1 [hp_X] in 100 g
MERCURIUS SOLUBILIS (UNII: 324Y4038G2) (MERCURIUS SOLUBILIS - UNII:324Y4038G2)	MERCURIUS SOLUBILIS	6 [hp_X] in 100 g
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	6 [hp_X] in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70857-004-16	454 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/19/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved		09/19/2016	

homeopathic

09/19/2010

Labeler - Medical Technology Products, Inc. (150890841)

Revised: 12/2021

Medical Technology Products, Inc.