

TENSION HEADACHE- aconitum napellus, carduus marianus, coffea cruda, dioscorea villosa, gelsemium sempervirens, gnaphalium polycephalum, iris versicolor, passiflora incarnata, stellaria media, verbascum thapsus spray Liddell Laboratories, 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.

DRUG FACTS:

ACTIVE INGREDIENTS:

(in each spray) 10% of Aconitum Napellus 200C, Carduus Marianus 3X, Coffea Cruda 200C, Dioscorea Villosa 3X, Gelsemium Sempervirens 3X, Gnaphalium Polycephalum 3X, Iris Versicolor 3X, Passiflora Incarnata 2X, Stellaria Media 3X, Verbascum Thapsus 12X.

PURPOSE:

May temporarily relieve symptoms of tension headaches:

- dull or sharp pain
- neck and shoulder tension
- feelings of pressure**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

WARNINGS:

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Stop use and ask a doctor if symptoms persist, worsen or if new symptoms occur.

Keep out of reach of children. In case of overdose, get medical help or call a Poison Control Center right away.

If pregnant or breast feeding, ask a doctor before using product.

Do not use if **TAMPER EVIDENT** seal around neck of bottle is missing or broken.

Store at room temperature.

KEEP OUT OF REACH OF CHILDREN:

In case of overdose, get medical help or call a Poison Control Center right away.

DIRECTIONS:

Adults and children over 12: Spray twice under the tongue up to each 30 minutes as needed.

Children 12 and under: Consult a doctor prior to use.

USES:

May temporarily relieve symptoms of tension headaches:

- dull or sharp pain
- neck and shoulder tension
- feelings of pressure**

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

INACTIVE INGREDIENTS:

Organic alcohol 20% v/v, Purified water.

QUESTIONS:

DIST. BY

LIDDELL LABORATORIES, INC.

201 APPLE BLVD.

WOODBINE, IA 51579

WWW.LIDDELL.NET

1-800-460-7733

PACKAGE LABEL DISPLAY:

ORAL SPRAYS

LIDDELL ®

LABORATORIES

EST. 1994

42 TH

Tension Headache

HOMEOPATHIC

1.0 FL OZ (30 ml)

INDICATIONS May temporarily relieve symptoms of tension headaches: dull or sharp pain, neck and shoulder tension, feelings of pressure.**

DIRECTIONS Adults & children over 12: Spray twice under the tongue up to each 30 minutes as needed. Children 12 and under: Consult a doctor prior to use.

WARNINGS See box. Do not use if TAMPER EVIDENT seal around neck of bottle is missing or broken.


ORAL SPRAYS
LIDDELL[®]
 ~ LABORATORIES ~
 EST. 1994
 42
TH[™]
 Tension Headache
 HOMEOPATHIC
 1.0 FL. OZ. (30 ml) 20% organic alcohol

ACTIVE INGREDIENTS (in each spray) 10% of Aconitum nap 200C, Carduus mar 3X, Coffea cruda 200C, Dioscorea 3X, Gelsemium 3X, Gnaphalium poly 3X, Iris vers 3X, Passiflora 2X, Stellaria med 3X, Verbasum 12X. **INACTIVE INGREDIENTS** Organic alcohol 20% v/v, Purified water.

**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.

DIST. BY LIDDELL LABORATORIES INC.
 WOODBINE, IA 51579
 WWW.LIDDELL.NET 1-800-460-7733

LOT: XXXXXX EXP: MM/YY

<p>Drug Facts (continued)</p> <p>Other information Store at room temperature.</p> <p>Inactive ingredients Organic alcohol 20% v/v, Purified water.</p> <p>Questions or comments? 1-800-460-7733 www.liddell.net</p>	<p>ORAL SPRAYS LIDDELL[®] ~ LABORATORIES ~ EST. 1994 42 TH[™] Tension Headache HOMEOPATHIC DOCTOR FORMULATED Readily absorbed. Safe. No known side effects. Easy to use. 1.0 FL. OZ. (30 ml) 20% organic alcohol</p>	<p>SPRAY YOUR WAY TO HEALTH[®]</p> <p>Oral sprays, a Liddell[®] innovation, are the modern and better way to deliver medication. Here's why:</p> <ul style="list-style-type: none"> • FAST ABSORPTION • EASY TO SWALLOW • ACCURATE-DOSE SPRAY PUMP • CONVENIENT • NO KNOWN NEGATIVE SIDE EFFECTS • NO KNOWN CONTRAINDICATIONS • NO KNOWN DRUG INTERACTIONS <p>Money Back Guarantee No questions asked! For details, visit: www.liddell.net</p> <p>**Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated.</p> <p>DIST. BY LIDDELL LABORATORIES INC. 201 APPLE BLVD. WOODBINE, IA 51579 WWW.LIDDELL.NET 1-800-460-7733</p> <p>MADE IN THE USA</p>  <p>3 63113 00496 0</p>	<p>Drug Facts</p> <p>Active ingredients Purposes <i>(in each spray)</i> 10% of Aconitum nap 200C, Carduus mar 3X, Coffea cruda 200C, Dioscorea 3X, Gelsemium 3X, Gnaphalium poly 3X, Iris vers 3X, Passiflora 2X, Stellaria med 3X, Verbasum 12X. (Symptom relief for tension headaches**)</p> <p>Uses May temporarily relieve symptoms of tension headaches:</p> <ul style="list-style-type: none"> • dull or sharp pain • neck and shoulder tension • feelings of pressure** <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Stop use and ask a doctor if symptoms persist, worsen or if new symptoms occur.</p> <p>Keep out of reach of children. In case of overdose, get medical help or call a Poison Control Center right away.</p> <p>If pregnant or breast feeding, ask a doctor before using product.</p> <p>Directions</p> <table border="1"> <tr> <td>Adults and children over 12</td> <td>Spray twice under the tongue up to each 30 minutes as needed.</td> </tr> <tr> <td>Children 12 and under</td> <td>Consult a doctor prior to use.</td> </tr> </table>	Adults and children over 12	Spray twice under the tongue up to each 30 minutes as needed.	Children 12 and under	Consult a doctor prior to use.
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TENSION HEADACHE

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spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50845-0276
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACONITUM NAPELLUS WHOLE (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS WHOLE	200 [hp_C] in 1 mL
MILK THISTLE (UNII: U946SH95EE) (MILK THISTLE - UNII:U946SH95EE)	MILK THISTLE	3 [hp_X] in 1 mL
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	200 [hp_C] in 1 mL
DIOSCOREA VILLOSA TUBER (UNII: IWY3IWX2G8) (DIOSCOREA VILLOSA ROOT - UNII:IWY3IWX2G8)	DIOSCOREA VILLOSA TUBER	3 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	3 [hp_X] in 1 mL
PSEUDOGNAPHALIUM OBTUSIFOLIUM WHOLE (UNII: 36XQ854NWM) (PSEUDOGNAPHALIUM OBTUSIFOLIUM - UNII:36XQ854NWM)	PSEUDOGNAPHALIUM OBTUSIFOLIUM WHOLE	3 [hp_X] in 1 mL
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	3 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS110) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS110)	PASSIFLORA INCARNATA FLOWERING TOP	2 [hp_X] in 1 mL
STELLARIA MEDIA (UNII: 2H03479QVR) (STELLARIA MEDIA - UNII:2H03479QVR)	STELLARIA MEDIA	3 [hp_X] in 1 mL
VERBASCUM THAPSUS WHOLE (UNII: C9TD27U172) (VERBASCUM THAPSUS - UNII:C9TD27U172)	VERBASCUM THAPSUS WHOLE	12 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50845-0276-2	1 in 1 CARTON	07/30/2024	11/21/2027
1	NDC:50845-0276-1	30 mL in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/30/2024	11/21/2027

Labeler - Liddell Laboratories, Inc. (832264241)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(50845-0276) , api manufacture(50845-0276) , label(50845-0276) , pack(50845-0276)

Revised: 11/2024

Liddell Laboratories, Inc.