

**TUMMY UPSET- chamomilla, echinacea, iris versicolor, ruta graveolens, taraxacum officinale, aloe, angelica sinensis radix, antimonium , argentum nitricum, arnica montana, arsenicum album, baptisia tinctoria, bismuthum metallicum, bryonia, cinchona officinalis, graphites, hydrastis canadensis, ipecacuanha, lachesis mutus, lycopodium clavatum, myrrha, natrum carbonicum, nux vomica, phosphorus, pulsatilla, zingiber officinale. liquid
Newton 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.

Tummy 1531L

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as nausea, "spitting up," vomiting, cramping, pain and gas.

DOSAGE & ADMINISTRATION SECTION

Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 drops) as needed or as directed by a health professional. Sensitive person begin with 1 drop and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

OTC - PURPOSE SECTION

Formulated for associated symptoms such as nausea, "spitting up," vomiting, cramping, pain and gas.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: USP Purified Water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

QUESTIONS SECTION

newtonlabs.net - Questions? 800.448.7256

Newton Laboratories, Inc. FDA Est # 1051203 Conyers, GA 30013

WARNINGS SECTION

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-feeding**, ask a doctor before use.

OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.


PACKAGE LABEL

newtonlabs.net ~ Questions? 800.448.7256

Newton Laboratories, Inc. FDA Est# 1051203 • Compex, GA 30013

Label statements have not been reviewed by the FDA.

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If pregnant or breast-feeding, ask a doctor before use.



NDC#
55714-1531-1

Tummy Upset

Formulated for associated symptoms such as nausea, "spitting up," vomiting, cramping, pain and gas.

1 FL OZ (30 ML)

Directions: Children, ages 0 to 11, give 3 drops by mouth (ages 12 and up, give 6 drops) as needed or as directed by a health professional. Sensitive persons begin with 1 drop and gradually increase to full dose.

Active Ingredients: Equal parts of Chamomilla 6x, Echinacea 6x, Iris vers. 6x, Ruta 6x, Taraxacum 6x, Aloe 15x, Angelica sin. 15x, Antimon. crud. 15x, Arg. nit. 15x, Arnica 15x, Arsenicum alb. 15x, Baptisia 15x, Bismuth. met. 15x, Bryonia 15x, Cinchona 15x, Graphites 15x, Hydrastis 15x, Ipecac. 15x, Lachesis 15x, Lycopodium 15x, Myrrha 15x, Nat. carb. 15x, Nux vom. 15x, Phos. 15x, Pulsatilla 15x, Zingiber 15x.

Inactive Ingredients: USP Purified water; USP Gluten-free, non-GMO, organic cane alcohol 20%.

Stock# **F020** Lot#

TUMMY UPSET

chamomilla, echinacea, iris versicolor, ruta graveolens, taraxacum officinale, aloe, angelica sinensis radix, antimonium, argentum nitricum, arnica montana, arsenicum album, baptisia tinctoria, bismuthum metallicum, bryonia, cinchona officinalis, graphites, hydrastis canadensis, ipecacuanha, lachesis mutus, lycopodium clavatum, myrrha, natrum carbonicum, nux vomica, phosphorus, pulsatilla, zingiber officinale. liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1531
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA CHAMOMILLA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	6 [hp_X] in 1 mL
SODIUM CARBONATE (UNII: 45P3261C7T) (CARBONATE ION - UNII:7UJQ5OPE7D)	SODIUM CARBONATE	15 [hp_X] in 1 mL
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	6 [hp_X] in 1 mL
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS FLOWERING TOP - UNII:N94C2U587S)	RUTA GRAVEOLENS FLOWERING TOP	6 [hp_X] in 1 mL
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 mL
ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)	ALOE	15 [hp_X] in 1 mL
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	15 [hp_X] in 1 mL
ANTIMONY TRISULFIDE (UNII: E70050A281) (ANTIMONY CATION (2+))		15 [hp_X]

ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY CATION (3+) - UNII:069647RPT5)	ANTIMONY TRISULFIDE	15 [hp_X] in 1 mL
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 mL
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 mL
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 mL
BAPTISIA TINCTORIA (UNII: 5K1UO2888Y) (BAPTISIA TINCTORIA - UNII:5K1UO2888Y)	BAPTISIA TINCTORIA	15 [hp_X] in 1 mL
BISMUTH (UNII: U015TT5I8H) (BISMUTH - UNII:U015TT5I8H)	BISMUTH	15 [hp_X] in 1 mL
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 mL
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 mL
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 mL
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 mL
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	15 [hp_X] in 1 mL
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 mL
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 mL
MYRRH (UNII: JC71GJ1F3L) (MYRRH - UNII:JC71GJ1F3L)	MYRRH	15 [hp_X] in 1 mL
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 mL
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 mL
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	15 [hp_X] in 1 mL
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 mL
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1531-1	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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unapproved homeopathic

01/01/2019

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-1531)

Revised: 2/2020

Newton Laboratories, Inc.