

**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. pellet
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 1731P

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 pellets by mouth (ages 12 and up, give 6 pellets) as needed or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive person begin with 1 pellet and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Chamomilla 6x, Echinacea 6x, Iris versicolor 6x, Ruta graveolens 6x, Taraxacum officinale 6x, Aloe 15x, Angelica sinensis radix 15x, Antimonium crudum 15x, Argentum nitricum 15x, Arnica montana 15x, Arsenicum album 15x, Baptisia tinctoria 15x, Bismuthum metallicum 15x, Bryonia 15x, Cinchona officinalis 15x, Graphites 15x, Hydrastis canadensis 15x, Ipecacuanha 15x, Lachesis mutus 15x, Lycopodium clavatum 15x, Myrrha 15x, Natrum carbonicum 15x, Nux vomica 15x, Phosphorus 15x, Pulsatilla 15x, Zingiber officinale 15x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, organic beet-derived sucrose (lactose-free) pellets.

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

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. pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1731
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 g
SODIUM CARBONATE (UNII: 45P3261C7T) (CARBONATE ION - UNII:7UJQ5OPE7D)	SODIUM CARBONATE	15 [hp_X] in 1 g
IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT - UNII:X43D4L3DQC)	IRIS VERSICOLOR ROOT	6 [hp_X] in 1 g
RUTA GRAVEOLENS FLOWERING TOP (UNII: N94C2U587S) (RUTA GRAVEOLENS	RUTA GRAVEOLENS	6 [hp_X]

FLOWERING TOP - UNII:N94C2U587S)	FLOWERING TOP	in 1 g
TARAXACUM OFFICINALE (UNII: 39981FM375) (TARAXACUM OFFICINALE - UNII:39981FM375)	TARAXACUM OFFICINALE	6 [hp_X] in 1 g
ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9)	ALOE	15 [hp_X] in 1 g
ANGELICA SINENSIS ROOT (UNII: B66F4574UG) (ANGELICA SINENSIS ROOT - UNII:B66F4574UG)	ANGELICA SINENSIS ROOT	15 [hp_X] in 1 g
ANTIMONY TRISULFIDE (UNII: F79059A38U) (ANTIMONY CATION (3+) - UNII:069647RPT5)	ANTIMONY TRISULFIDE	15 [hp_X] in 1 g
SILVER NITRATE (UNII: 95IT3W8JZE) (SILVER CATION - UNII:57N7B0K90A)	SILVER NITRATE	15 [hp_X] in 1 g
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW)	ARNICA MONTANA	15 [hp_X] in 1 g
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 g
BAPTISIA TINCTORIA (UNII: 5K1UO2888Y) (BAPTISIA TINCTORIA - UNII:5K1UO2888Y)	BAPTISIA TINCTORIA	15 [hp_X] in 1 g
BISMUTH (UNII: U015TT5I8H) (BISMUTH - UNII:U015TT5I8H)	BISMUTH	15 [hp_X] in 1 g
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 g
CINCHONA OFFICINALIS BARK (UNII: S003A158SB) (CINCHONA OFFICINALIS BARK - UNII:S003A158SB)	CINCHONA OFFICINALIS BARK	15 [hp_X] in 1 g
GRAPHITE (UNII: 4QQN74LH4O) (GRAPHITE - UNII:4QQN74LH4O)	GRAPHITE	15 [hp_X] in 1 g
GOLDENSEAL (UNII: ZW3Z11D0JV) (GOLDENSEAL - UNII:ZW3Z11D0JV)	GOLDENSEAL	15 [hp_X] in 1 g
IPECAC (UNII: 62I3C8233L) (IPECAC - UNII:62I3C8233L)	IPECAC	15 [hp_X] in 1 g
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 g
LYCOPODIUM CLAVATUM SPORE (UNII: C88X29Y479) (LYCOPODIUM CLAVATUM SPORE - UNII:C88X29Y479)	LYCOPODIUM CLAVATUM SPORE	15 [hp_X] in 1 g
MYRRH (UNII: JC71GJ1F3L) (MYRRH - UNII:JC71GJ1F3L)	MYRRH	15 [hp_X] in 1 g
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 g
ANEMONE PULSATILLA (UNII: I76KB35JEV) (ANEMONE PULSATILLA - UNII:I76KB35JEV)	ANEMONE PULSATILLA	15 [hp_X] in 1 g
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	15 [hp_X] in 1 g
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
ECHINACEA, UNSPECIFIED (UNII: 4N9P6CC1DX) (ECHINACEA, UNSPECIFIED - UNII:4N9P6CC1DX)	ECHINACEA, UNSPECIFIED	6 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-1731-1	28 g 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
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(55714-1731)

Revised: 2/2020

Newton Laboratories, Inc.