

**TUMMY UPSET - bismuthum metallicum, aloe, angelica sinensis radix, antimon. crud., arg. nit., arnica, arsenicum alb., baptisia, bryonia, cinchona, graphites, hydrastis, ipecac., lachesis, lycopodium, myrrha, nat. carb., nux vom., phosphorus, pulsatilla, zingiber, chamomilla, echinacea, iris versicolor, ruta, taraxacum 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 Upset

INDICATIONS & USAGE SECTION

Tummy Upset Formulated for symptoms associated with digestive discomfort such as nausea, "spitting up", vomiting, cramping, pain and gas.

DOSAGE & ADMINISTRATION SECTION

Directions: Children, ages 0 to 11, give 3 pellets orally (ages 12 and up, give 6 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

OTC - ACTIVE INGREDIENT SECTION

Bismuthum metallicum 15x, Aloe 10x, Angelica sinensis radix 10x, Antimon. crud. 10x, Arg. nit. 10x, Arnica 10x, Arsenicum alb. 10x, Baptisia 10x, Bryonia 10x, Cinchona 10x, Graphites 10x, Hydrastis 10x, Ipecac. 10x, Lachesis 10x, Lycopodium 10x, Myrrha 10x, Nat. carb. 10x, Nux vom. 10x, Phosphorus 10x, Pulsatilla 10x, Zingiber 10x, Chamomilla 3x, Echinacea 3x, Iris versicolor 3x, Ruta 3x, Taraxacum 3x.

OTC - PURPOSE SECTION

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

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

QUESTIONS SECTION

www.newtonlabs.net Newton Laboratories, Inc. FDA Est # 1051203 - Conyers, GA 30012
Questions? 1.800.448.7256

WARNINGS SECTION

Warning: Do not use if tamper - evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

OTC - PREGNANCY OR BREAST FEEDING SECTION

Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.

PACKAGE LABEL

www.newtonlabs.net
 Newton Laboratories, Inc. FDA Est#1051203 • Conyers, GA 30012
Questions? 1.800.448.7256
 Warnings: Do not use if tamper-evident seal is broken or missing. Consult a licensed healthcare professional if pregnant, nursing or if symptoms worsen or persist for more than a few days. Keep out of reach of children.

NEWTON homeopathics[™] for Kids
 Nurturing Naturally Since 1987[™]
 NDC# 55714-1708-1

Tummy Upset

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

1 oz (28.35 g)

Directions: Children, ages 0 to 11, give 3 pellets orally (ages 12 and up, give 6 pellets) as needed or as directed by a healthcare professional. Under age 2, crush or dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

Active Ingredients: Bismuthum metallicum 15x, Aloe 10x, Angelica sinensis radix 10x, Antimon. crud. 10x, Arg. nit. 10x, Arnica 10x, Arsenicum alb. 10x, Baptisia 10x, Bryonia 10x, Cinchona 10x, Graphites 10x, Hydrastis 10x, Ipecac. 10x, Lachesis 10x, Lycopodium 10x, Myrrha 10x, Nat. carb. 10x, Nux vom. 10x, Phosphorus 10x, Pulsatilla 10x, Zingiber 10x, Chamomilla 3x, Echinacea 3x, Iris versicolor 3x, Ruta 3x, Taraxacum 3x.

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose pellets.

Stock# **F020** Lot#

TUMMY UPSET

bismuthum metallicum, aloe, angelica sinensis radix, antimon. crud., arg. nit., arnica, arsenicum alb., baptisia, bryonia, cinchona, graphites, hydrastis, ipecac., lachesis, lycopodium, myrrha, nat. carb., nux vom., phosphorus, pulsatilla, zingiber, chamomilla, echinacea, iris versicolor, ruta, taraxacum pellet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-1708
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bismuth (UNII: U015TT5I8H) (Bismuth - UNII:U015TT5I8H)	Bismuth	15 [hp_X] in 1 g
Aloe (UNII: V5VD430YW9) (Aloe - UNII:V5VD430YW9)	Aloe	10 [hp_X] in 1 g
Angelica Sinensis Root (UNII: B66F4574UG) (Angelica Sinensis Root - UNII:B66F4574UG)	Angelica Sinensis Root	10 [hp_X] in 1 g

Antimony Trisulfide (UNII: F79059A38U) (Antimony Trisulfide - UNII:F79059A38U)	Antimony Trisulfide	10 [hp_X] in 1 g
Silver Nitrate (UNII: 95IT3W8JZE) (Silver Cation - UNII:57N7B0K90A)	Silver Nitrate	10 [hp_X] in 1 g
Arnica Montana (UNII: O80TY208ZW) (Arnica Montana - UNII:O80TY208ZW)	Arnica Montana	10 [hp_X] in 1 g
Arsenic Trioxide (UNII: S7V92P67HO) (Arsenic Cation (3+) - UNII:C96613F5AV)	Arsenic Trioxide	10 [hp_X] in 1 g
Baptisia Tinctoria (UNII: 5K1UO2888Y) (Baptisia Tinctoria - UNII:5K1UO2888Y)	Baptisia Tinctoria	10 [hp_X] in 1 g
Bryonia Alba Root (UNII: T7J046YI2B) (Bryonia Alba Root - UNII:T7J046YI2B)	Bryonia Alba Root	10 [hp_X] in 1 g
Cinchona Officinalis Bark (UNII: S003A158SB) (Cinchona Officinalis Bark - UNII:S003A158SB)	Cinchona Officinalis Bark	10 [hp_X] in 1 g
Graphite (UNII: 4QQN74LH4O) (Graphite - UNII:4QQN74LH4O)	Graphite	10 [hp_X] in 1 g
Goldenseal (UNII: ZW3Z11D0JV) (Goldenseal - UNII:ZW3Z11D0JV)	Goldenseal	10 [hp_X] in 1 g
Ipecac (UNII: 62IBC8233L) (Ipecac - UNII:62IBC8233L)	Ipecac	10 [hp_X] in 1 g
Lachesis Muta Venom (UNII: VSW71SS07I) (Lachesis Muta Venom - UNII:VSW71SS07I)	Lachesis Muta Venom	10 [hp_X] in 1 g
Lycopodium Clavatum Spore (UNII: C88X29Y479) (Lycopodium Clavatum Spore - UNII:C88X29Y479)	Lycopodium Clavatum Spore	10 [hp_X] in 1 g
Myrrh (UNII: JC71GJ1F3L) (Myrrh - UNII:JC71GJ1F3L)	Myrrh	10 [hp_X] in 1 g
Sodium Carbonate (UNII: 45P3261C7T) (Carbonate Ion - UNII:7UJQ5OPE7D)	Sodium Carbonate	10 [hp_X] in 1 g
Strychnos Nux-vomica Seed (UNII: 269XH13919) (Strychnos Nux-vomica Seed - UNII:269XH13919)	Strychnos Nux-vomica Seed	10 [hp_X] in 1 g
Phosphorus (UNII: 27YLU75U4W) (Phosphorus - UNII:27YLU75U4W)	Phosphorus	10 [hp_X] in 1 g
Pulsatilla Vulgaris (UNII: I76KB35JEV) (Pulsatilla Vulgaris - UNII:I76KB35JEV)	Pulsatilla Vulgaris	10 [hp_X] in 1 g
Ginger (UNII: C5529G5JPQ) (Ginger - UNII:C5529G5JPQ)	Ginger	10 [hp_X] in 1 g
Matricaria Recutita (UNII: G0R4UBI2ZZ) (Matricaria Recutita - UNII:G0R4UBI2ZZ)	Matricaria Recutita	3 [hp_X] in 1 g
Echinacea, Unspecified (UNII: 4N9P6CC1DX) (Echinacea, Unspecified - UNII:4N9P6CC1DX)	Echinacea, Unspecified	3 [hp_X] in 1 g
Iris Versicolor Root (UNII: X43D4L3DQC) (Iris Versicolor Root - UNII:X43D4L3DQC)	Iris Versicolor Root	3 [hp_X] in 1 g
Ruta Graveolens Flowering Top (UNII: N94C2U587S) (Ruta Graveolens Flowering Top - UNII:N94C2U587S)	Ruta Graveolens Flowering Top	3 [hp_X] in 1 g
Taraxacum Officinale (UNII: 39981FM375) (Taraxacum Officinale - UNII:39981FM375)	Taraxacum Officinale	3 [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:55714-1708-1	28.35 g in 1 BOTTLE, GLASS		
2	NDC:55714-1708-2	56.7 g in 1 BOTTLE, GLASS		

3	NDC:55714-1708-0	7.08 g in 1 BOTTLE, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		03/01/2011		

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment			
Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	MANUFACTURE(55714-1708)

Revised: 3/2011

Newton Laboratories, Inc.