

**STOMASIN- gypsum fibrosum extract, forsythia viridissima fruit extract, arctium lappa fruit extract, platycodon grandiflorus root extract, saposchnikovia divaricata root extract, glycyrrhiza uralensis root extract, ostericum koreanum extract, schizonepeta tenuifolia extract capsule, coated
MedicareBio.Co.Ltd**

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.

82871-301-01 Stomasin

Active Ingredients

Gypsum fibrosum extract, Forsythia viridissima fruit extract, Arctium lappa fruit extract, Platycodon grandiflorus root extract, Saposchnikovia divaricata root extract, Glycyrrhiza uralensis root extract, Ostericum koreanum extract, Schizonepeta tenuifolia extract

Purpose

antipyretic, anti-inflammatory, anti-corona virus (omicron variant)

Uses

for swelling and sore throat symptoms

temporarily reduces fever; relieves swelling and sore throat for tonsillitis / peritonsillitis

Warnings

Do not use in the following patients

Because this drug contains lactose, it should not be administered to patients with genetic problems such as galactose intolerance, lactose intolerance, or glucose-galactose malabsorption.: See Insert Paper

Warnings

Keep out of reach of children

Warnings

In the following cases, stop using this drug immediately and consult a doctor, carry this Insert Paper with you. : See Insert Paper

Warnings

The following people should not use this drug. Infants under 3 months

The following people should consult with a doctor before use if you have .: See Insert Paper

Warnings

Storage precautions : See Insert Paper

If pregnant or breast-feeding, ask a health professional before use

In case of overdose, get medical help or contact a Poison Control Center immediately

Directions

Adults Take 2 capsules per time, 3 times a day

Children 7 years to under 14 years 2/3 of the adult dose (4/3 capsules)

Children 4 years to under 6 years 1/2 of the adult dose (1 capsule)

Children 2 years to under 3 years 1/3 of the adult dose (2/3 capsule)

Children under 1 years 1/4 of the adult dose (1/2 capsule)

Dissolve it in lukewarm water before or between meals (between meals and between meals) and take it slowly in small portions while moistening the mouth or throat (do not swallow capsules).

Other Information

protect from excessive moisture, store at 1~30°C(33.8~86°F)

Inactive Ingredients

FD&C blue no.1, FD&C blue no.3, FD&C yellow no.5, lactose hydrate (cow, milk), magnesium stearate, silicon dioxide, gelatin

Display Panel

Drug Facts	
Active Ingredients (in each capsule)	Purpose
Gypsum fibrosum extract1,665mg	antipyretic
Forsythia viridissima fruit extract835mg	anti-inflammatory
Arctium lappa fruit extract500mg	anti-inflammatory, antipyretic
Platycodon grandiflorus root extract500mg	anti-inflammatory
Saposhnikovia divaricata root extract500mg	anti-inflammatory, antipyretic
Glycyrrhiza uralensis root extract250mg	anti-corona virus (omicron variant)
Ostericum koreanum extract250mg	anti-inflammatory
Schizonepeta tenuifolia extract250mg	anti-inflammatory, antipyretic
in mixed dry extract 685mg	
Uses for swelling and sore throat symptoms	
■ temporarily reduces fever; relieves swelling and sore throat for tonsillitis / peritonsillitis.	

warnings

1. Do not use in the following patients

Because this drug contains lactose, it should not be administered to patients with genetic problems such as galactose intolerance, lactose intolerance, or glucose-galactose malabsorption.: See Insert Paper

2. The following people should not use this drug. Infants under 3 months

3. The following people should consult with a doctor before use if you have .: See Insert Paper

4. In the following cases, stop using this drug immediately and consult a doctor, carry this Insert Paper with you. : See Insert Paper

5. Other precautions when taking this drug : See Insert Paper

6. Storage precautions : See Insert Paper

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children In case of overdose, get medical help or contact a Poison Control Center immediately

Direction

Adults	Take 2 capsules per time, 3 times a day
Children 7 years to under 14 years	2/3 of the adult dose (4/3 capsules)
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Children under 1 years	1/4 of the adult dose (1/2 capsule) Dissolve it in lukewarm water before or between meals (between meals and between meals) and take it slowly in small portions while moistening the mouth or throat (do not swallow capsules).

Drug Facts (continued)**Other Information**

▪ protect from excessive moisture, store at 1~30°C (33.8~86°F)

Inactive ingredients

■ Additives (tar color) : FD&C blue no. 1, FD&C blue no. 3, FD&C yellow no. 5 ■ Additives (Animal-derived Products) : Lactose hydrate (cow, milk) ■ Other additives : Magnesium Stearate, Silicon dioxide, Capsule

STOMASIN

gypsum fibrosum extract, forsythia viridissima fruit extract, arctium lappa fruit extract, platycodon grandiflorus root extract, saposchnikovia divaricata root extract, glycyrrhiza uralensis root extract, ostericum koreanum extract, schizonepeta tenuifolia extract capsule, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82871-301
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OSTERICUM GROSSESERRATUM ROOT (UNII: 9IGM98814N) (OSTERICUM GROSSESERRATUM ROOT - UNII:9IGM98814N)	OSTERICUM GROSSESERRATUM ROOT	250 mg
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0DDB505) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM SULFATE, UNSPECIFIED FORM	1665 mg
FORSYTHIA VIRIDISSIMA FRUIT (UNII: P4ZY00SWES) (FORSYTHIA VIRIDISSIMA FRUIT - UNII:P4ZY00SWES)	FORSYTHIA VIRIDISSIMA FRUIT	835 mg
ARCTIUM LAPPA FRUIT (UNII: EA541308MV) (ARCTIUM LAPPA FRUIT - UNII:EA541308MV)	ARCTIUM LAPPA FRUIT	500 mg
PLATYCODON GRANDIFLORUM ROOT (UNII: 2DF0NS002Z) (PLATYCODON GRANDIFLORUM ROOT - UNII:2DF0NS002Z)	PLATYCODON GRANDIFLORUM ROOT	500 mg
SAPOSHNIKOVIA DIVARICATA ROOT (UNII: 8H84LFK2QD) (SAPOSHNIKOVIA DIVARICATA ROOT - UNII:8H84LFK2QD)	SAPOSHNIKOVIA DIVARICATA ROOT	500 mg
NEPETA TENUIFOLIA FLOWERING TOP (UNII: 2FN3BA1MZE) (NEPETA TENUIFOLIA FLOWERING TOP - UNII:2FN3BA1MZE)	NEPETA TENUIFOLIA FLOWERING TOP	250 mg
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K) (GLYCYRRHIZA URALENSIS ROOT - UNII:42B5YD8F0K)	GLYCYRRHIZA URALENSIS ROOT	250 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

Product Characteristics			
Color	blue (blue and dark green capsule)	Score	score with uneven pieces
Shape	CAPSULE (brown powder encapsulated in blue and dark green opaque capsule)	Size	22mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82871-301-01	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/13/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/13/2022	

Labeler - MedicareBio.Co.Ltd (695630697)

Registrant - MedicareBio.Co.Ltd (695630697)

Establishment

Name	Address	ID/FEI	Business Operations
MedicareBio.Co.Ltd		695630697	manufacture(82871-301)

Revised: 12/2023

MedicareBio.Co.Ltd