

ASTONEA GREEN GEL- menthol gel
ASTONEA LABS PRIVATE LIMITED

ASTONEA GREEN PAIN GEL

Drug Facts

Active Ingredients

Menthol 5%

Purpose

Pain Relieving

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

■ Simple backache

Arthritis ■ Strains ■ Bruises ■ Sprains

Warnings

For external use only

Flammable:

Keep away from excessive heat or open flame.

When using this product:

■ Use only as directed

■ Avoid contact with the eyes or on mucous membranes

■ Do not apply to wounds or damaged skin

■ Do not apply to irritated skin or if excessive irritation develops ■ Do not bandage tightly or use with heating pad or device

Stop use and ask a doctor if:

■ You experience pain, swelling or blistering of the skin

■ Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

■ Arthritis pain persists for more than 10 days or redness is present, or in conditions affecting children under 12 years of age

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ **Adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily** ■ **Children under 2 years**

of age: consult a physician ■ **Wash hands after use with cool water**

■ **Store at 20°-25°C (68°-77°F)**

■ **Store in a cool dry place away from direct sunlight**

Inactive Ingredients

: Aloe Vera Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Calendula Officinalis Extract, Carbopol, FD&C Blue No. 1, FD&C Yellow No. 5, Glycerine, Green Tea Extract, Isopropyl Alcohol, Isopropyl Myristate, Silica, Triethanolamine, Vitamin E, Water

Package Labeling:

ASTONEA

GREEN PAIN RELIEF GEL

Helps relieve minor aches and pains of muscles and joints

with Menthol

NET WT.: 4 FL. OZ. (118ML)

Drug Facts	Purpose
Active ingredient Menthol (5%w/w).....	Pain Relieving
Uses Temporarily relieves minor aches and pains of muscles and joints associated with: ■ Simple backache ■ Arthritis ■ Strains ■ Bruises ■ Sprains	
Warnings: For external use only.	
Flammable: Keep away from excessive heat or open flame	
When using this product ■ Use only as directed ■ Avoid contact with the eyes or on mucous membranes ■ Do not apply to wounds or damaged skin ■ Do not apply to irritated skin or if excessive irritation develops ■ Do not bandage tightly or use with heating pad or device	
Stop use and consult a doctor if: ■ You experience pain, swelling or blistering of the skin ■ Condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days ■ Arthritis pain persists for more than 10 days or redness is present, or in conditions affecting children under 12 years of age	
If pregnant or breast-feeding, ask a health care professional before use.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Adults and children 2 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily ■ Children under 2 years of age: consult a physician ■ Wash hands after use with cool water	
Other information ■ Store at 20°-25°C (68°-77°F) ■ Store in a cool dry place away from direct sunlight	
Inactive Ingredients: Aloe Vera Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Calendula Officinalis Extract, Carpopal, FD&C Blue No. 1, FD&C Yellow No. 5, Glycerine, Green Tea Extract, Isopropyl Alcohol, Isopropyl Myristate, Silica, Triethanolamine, Vitamin E, Water	

GREEN PAIN RELIEF GEL

NET WT.: 4 FL. OZ. (118ML)

Manufactured by:

Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station, Panchkula,
Haryana, India - 134204

Made in India

HR/OL/US 1105-05PHH

ASTONEA GREEN GEL

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARCTIUM LAPPA ROOT (UNII: 597E9BI3Z3)	

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-015-65	113 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2022	
2	NDC:77338-015-67	907 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/19/2022	
3	NDC:77338-015-63	2.9 g in 1 POUCH; Type 0: Not a Combination Product	09/19/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/19/2016	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)