

ASTONEA GREEN GEL- menthol gel
ASTONEA LABS PRIVATE LIMITED

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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.	
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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: Aloevera 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: ETJ7Z6XB4)	
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)	
CARBOXPOLYMETHYLENE (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 not final	part348	09/19/2016	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 9/2022

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