NUMSTAT ANTISEPTIC AND PAIN RELIEVING PREP PAD- alcohol, menthol, and benzocaine prep pad swab Spectra Medical Devices, LLC

Antiseptic & Pain Relieving Prep Pad

Active Ingredients

Active Ingredients (per application in each pad)

Percent Purpose

Benzocaine...... 15% Topical Analgesic

Purpose

Antiseptic & Pain Relieving

Uses

Uses

• For the temporary relief of pain associated with needle sticks, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, and insect bites • Reduces the risk of infection • Kills germs

Warnings

Warnings

Flammable. Keep away from heat or open flame.

When using this product • Use glove with application hand or always wash application hand immediately after application

For external use only

Do Not Use

Do not use • Avoid contact with eyes, mouth, or mucous membranes. In case of contact with eyes, mouth, or mucous membranes, flush with water, call a doctor.

Stop use

Discontinue use if irritation occurs. If condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use and consult a doctor.

Keep out of reach of children

Keep out of reach of children. If swallowed, call a doctor or poison control center.

Directions

Directions for Use

Adults and children 2 years of age and older.

- Apply to affected area. Do not apply more than 4 times daily.
- Apply pad solution to the skin and gently rub in and let dry.
- Test for effect by touching area before performing procedure

May need to reapply on certain skin types.

For children under 2 years of age, consult a doctor.

Other Information

Other Information

Protect from excessive heat.

Inactive Ingredients

Inactive Ingredients

Neopentyl Glycol Diheptanoate

Neopentyl Glycol Diheptanoate Isododecane

Purified Water

Questions or Comments?

Ouestions or Comments?

Call (978) 657-0889 or visit num-stat.com

Carton Information

Antiseptic & Pain Relieving Prep Pad

NUMSTAT

Fast Needle Pain Relief

- Quickly Relieve Minor Topical Pain with 15% Benzocaine and 1% Menthol
- Easily Clean and Kill Germs with 71% Isopropyl Alcohol

Afraid of Needle Pain?

To Relieve Minor

Topical Pain Fast,

Gently Rub In and Let Dry!

Manufactured for:

Spectra Medical Devices, LLC

299 Ballardvale Street, Suite 1, Wilmington, MA 01887

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Package Label Principal Display Panel



NUMSTAT Carton



Manufactured for:

Spectra Medical Devices, LLC, 299 Ballardvale Street, STE 1, Wilmington, MA 01887 Phone: (978) 657-0889 NUMSTAT is a Trademark of Spectra Medical Devices, LLC. © 2023, Spectra Medical Devices, LLC. All Rights Reserved.

Drug Facts

Active Ingredients (per application in each past)

Purpose

Isopropyl Alcohol 71% Antiseptic Benzocalne 15% Topical Analgesic Menthol 1% Topical Analgesic

US6S For temporary relief of pain associated with needle sticks, minor burns, sunburn, minor cuts, scrapes, minor sidn irritations, and insect bites Reduces the risk of infection • Kills germs

Warnings

For external use only • Flammable.

Keep away from heat or open flame. Do not use Avoid contact with eyes, mouth, or mucous membranes.
 In case of contact with eyes, mouth, or mucous membranes, flush with water, call a doctor. . Keep out of reach of children. If swallowed, call a doctor or polson control center.

Keep box for complete Drug Facts

NUMSTAT ANTISEPTIC AND PAIN RELIEVING PREP PAD

alcohol, menthol, and benzocaine prep pad swab

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65282-1815

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) BENZOCAINE (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302) ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL

1 g in 100 g

Inactive Ingredients

Ingredient Name Strength

WATER (UNII: 059QF0KO0R)

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:65282- 1815-1	30 in 1 CARTON	01/01/2023					
1		1 g in 1 PACKET; Type 0: Not a Combination Product						
2	NDC:65282- 1815-2	100 in 1 CARTON	01/01/2023					
2		1 g in 1 PACKET; Type 0: Not a Combination Product						

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC Monograph Drug	M003	01/01/2023						

Labeler - Spectra Medical Devices, LLC (118301171)

Registrant - Spectra Medical Devices, LLC (118301171)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec Of America Inc.		874965262	manufacture(65282-1815)

Revised: 12/2023 Spectra Medical Devices, LLC