ZENSA NUMBING GEL- lidocaine 5%, phenylephrine hydrochloride 0.25% gel Alera Skin Care Products Inc.

Active Ingredient

Lidocaine 5% and Phenylephrine hydrochloride 0.25%

PURPOSE

Local Anaesthetic

Vasoconstrictor

Protective

USES

For temporary relief of local discomfort associated with anorectal disorders. For temporary

relief of pain, soreness and burning. Temporarily shrinks hemorrhoidal tissue.

WARNINGS

For external use only.

Before use ask a doctor:

• if you are presently taking a prescription drug for high blood pressure or depression.

When using this product:

- •certain persons can develop allergic reactions to ingredients in this product.
- if the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

Stop use and ask a doctor if:

- •condition worsens or does not improve within 7 days
- •bleeding occurs.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

Children under 12 years of age: Consult a doctor.

Apply externally to the affected area up to 4 times daily.

STORAGE AND HANDLING

Other Information

See enclosed consumer leaflet prior to use. Store at 59°-86°F. Protect from freezing.

INACTIVE INGREDIENT

Benzyl Alcohol, Carbomer, Caprylyl Glycol, Propylene Glycol, Phenoxyethanol, Purified Water.

QUESTIONS

Questions? 1-844-441-7546

Zensa Numbing Gel 1 oz





lidocaine 5%, phenylephrine hydrochloride 0.25% gel

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69805-400 | |
| Route of Administration | RECTAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|--------------------------------|--------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 0.25 g in 100 g | |
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 5 g in 100 g | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | | |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) | | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | | |
| WATER (UNII: 059QF0KO0R) | | |

| F | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:69805-400- 01 | 1 in 1 CARTON | 09/25/2023 | | | |
| 1 | | 30 g in 1 TUBE; Type 0: Not a Combination Product | | | | |

| Marketing Information | | | | |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M015 | 09/25/2023 | | |
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Labeler - Alera Skin Care Products Inc. (202686093)

Revised: 9/2023 Alera Skin Care Products Inc.