

HARRIS TEETER TRIPLE ANTIBIOTIC PLUS PAIN RELIEF- neomycin, polymyxin b, and pramoxine hcl cream

Harris Teeter

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.

Active ingredients (in each gram)

Purpose

Neomycin 3.5 mg.....	First aid antibiotic
Polymyxin B 10,000 units.....	First aid antibiotic
Pramoxine HCl 10 mg.....	External analgesic

☐ **Uses** ☐ first aid to help prevent infection and for temporary relief of pain or discomfort in minor:

- cuts
- scrapes
- burns☐

☐ **Warnings**

For external use only.☐

☐ **Do not use**

- ☐if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body

☐ **Ask a doctor before use if you have**

- ☐deep or puncture wounds
- animal bites
- serious burns

☐ **Stop use and ask a doctor if**

- ☐you need to use longer than 1 week
- condition persists or gets worse
- symptoms persist for more than 1 week, or clear up, and occur again within a few days
- rash or other allergic reaction develops

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:
- clean the affected area
- apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

☐ **Other information**

- ☐store at 20° to 25°C (68° to 77°F)
- lot no. & exp. date: see box or see crimp of tube

Inactive ingredients

- cetyl alcohol, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, sorbitan monostearate, stearic acid, water

Distributed by:

Harris Teeter, LLC

Matthews, NC 28105

Made in Korea

Maximum Strength
Triple Antibiotic + Pain Relief Cream

<p>Drug Facts</p> <p>Active ingredients (in each gram) Purpose</p> <p>Neomycin 3.5 mg First aid antibiotic</p> <p>Polymyxin B 10,000 units First aid antibiotic</p> <p>Pramoxine HCl 10 mg External analgesic</p>		<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> symptoms persist for more than 1 week, or clear up and occur again within a few days rash or other allergic reaction develops <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Uses first aid to help prevent infection and for temporary relief of pain or discomfort in minor:</p> <ul style="list-style-type: none"> cuts scrapes burns 	<p>Directions</p> <ul style="list-style-type: none"> adults and children 2 years of age and older: <ul style="list-style-type: none"> clean the affected area apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily may be covered with a sterile bandage children under 2 years of age: ask a doctor 	
<p>Warnings</p> <p>For external use only.</p> <p>Do not use</p> <ul style="list-style-type: none"> if you are allergic to any of the ingredients in the eyes over large areas of the body <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> deep or puncture wounds animal bites serious burns <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you need to use longer than 1 week condition persists or gets worse 	<p>Other information</p> <ul style="list-style-type: none"> store at 20° to 25°C (68° to 77°F) lot no. & exp. date: see box or see crimp of tube <p>Inactive ingredients cetyl alcohol, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, sorbitan monostearate, stearic acid, water</p> <p>Questions or comments? Call 1-800-814-8028</p>	

*This product is not manufactured or distributed by Johnson & Johnson Consumer, Inc., owner of the trademark Neosporin® + Pain Relief Cream.

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HARRIS TEETER, LLC
MATTHEWS, NC 28105
MADE IN KOREA

yourplusguarantee.

NET WT 0.5 OZ (14 g)
Helps relieve painful cuts, scrapes, and burns

Triple Antibiotic + Pain Relief Cream

Neomycin Sulfate | Polymyxin B Sulfate | Pramoxine HCl
First Aid Antibiotic + Pain Relief
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neomycin, polymyxin b, and pramoxine hcl cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USPU] in 1 g
PRAMO XINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMO XINE - UNII:068X84E056)	PRAMO XINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-403-14	1 in 1 CARTON	04/20/2017	
1		14 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 not final	part348	04/20/2017	

Labeler - Harris Teeter (047279351)

Revised: 4/2017

Harris Teeter