ANTIBIOTICS (TOPICAL) LABELLING STANDARD

CATEGORY:  TOPICAL ANTIBIOTICS FOR FIRST AID USE

DEFINITION:  First aid antibiotic: an antibiotic-containing drug product, suitable for self-medication, which is applied topically to the skin to help prevent infection in minor cuts, scrapes and burns.

Antibiotic drug: any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism (including the chemically synthesized equivalent of any such substance) and which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

MEDICINAL INGREDIENTS:

Pharmaceutical Forms: cream, ointment, aerosol, powder

All finished product and ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this standard consist of the following ingredients when used singly or in acceptable combinations within the established limits given:

SINGLE INGREDIENT PRODUCTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration: (/g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin</td>
<td>400 - 500 units</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>400 - 500 units</td>
</tr>
<tr>
<td>Mupirocin</td>
<td>2%</td>
</tr>
</tbody>
</table>

MULTI-INGREDIENT PRODUCTS

<table>
<thead>
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<tr>
<td>Bacitracin</td>
<td>400 - 500 units</td>
</tr>
<tr>
<td>Bacitracin Zinc</td>
<td>400 - 500 units</td>
</tr>
<tr>
<td>Polymixin B Sulfate</td>
<td>5,000 &amp; 10,000 units</td>
</tr>
<tr>
<td>Gramicidin</td>
<td>0.25 mg</td>
</tr>
</tbody>
</table>

PERMITTED COMBINATIONS:

Combinations of antibiotic active ingredients:

Polymixin B Sulfate + Gramicidin
Polymixin B Sulfate + Bacitracin
Polymixin B Sulfate + Bacitracin Zinc

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Combinations with local anesthetic active ingredients:

Any of the above topical antibiotic ingredients (single or permitted combinations) with one of the following local anesthetic active ingredients:

- Benzocaine 5 to 20 %
- Butamben picrate 1 %
- Dibucaine or Dibucaine HCl 0.25 to 1 %
- Dimethisoquin HCl 0.3 to 0.5 %
- Dyclonine HCl 0.5 to 1 %
- Lidocaine or Lidocaine HCl 0.5 to 4 %
- Pramoxine HCl 0.5 to 1 %
- Tetracaine or Tetracaine HCl 1 to 2 %

ADEQUATE DIRECTIONS FOR USE:

Indications: The inner and outer labels shall bear a statement of the indications for use to the effect:

- first aid to help prevent infection in minor cuts, scrapes and burns.
- first aid to help reduce the risk of infection in minor cuts, scrapes and burns.
- helps prevent infection and aids healing of minor cuts, scrapes and burns.

In addition, the claim "topical antibiotic" will be considered acceptable, but should be in addition to one of the aforementioned claims.

For those products that also contain local anesthetics, the following additional indication should be used:

- first aid for the temporary relief of (pain, discomfort and/or itching) in minor cuts, scrapes and burns.

Dosage Directions: The inner and outer labels shall carry a statement that indicates that:

- for ointment and cream products -
  - clean 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, as required. May be covered with a sterile bandage.

- **for aerosol products** -
  # clean affected area. Spray a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.

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- **for powder products** -
  # clean affected area. Apply a light dusting of the powder on the area 1 to 3 times daily. May be covered with a sterile bandage.

**Expiry date:** (section C.01.401)

**Warnings:** The inner and outer labels shall carry a statement, to the effect:
  # if irritation occurs or the condition persists or gets worse, stop use and consult a doctor
  # for external use only.
  # do not apply over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor
  # contact with eyes should be avoided. If this happens rinse thoroughly with water
  # do not use longer than 1 week, unless directed by a doctor

**NOTE:** This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

**REFERENCES:**


2. **Compendium of Pharmaceuticals and Specialties**, 27th Edition,
1992, Canadian Pharmaceutical Association


5 United States Federal Register Vol. 52, No. 238 December 11, 1987 pp 47312-47324. Topical Antimicrobial Drug Products for Over-the-counter Human Use; Final Monograph for OTC First Aid Antibiotic Drug Products; Final Rule


12 AMA Drug Evaluations Annual, 1992, American Medical Association


Bureau of Nonprescription Drugs
November 19, 1992