

**OBSTETRICAL ANTISEPTIC - benzalkonium chloride swab**  
**Wuxi Medical Instrument Factory**

*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.*

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**Drug Facts**

Item# 83791-510-003    NDC#42947-630-03    Qty.1ea

**Obstetrical Antiseptic Towelette**

Contains: Benzalkonium Chloride 0.13%

For Single Use Only

Caution: Keep out of reach of children

Manufactured by: Wuxi Medical Instrument Factory

No.86 East street, Zhangjing, Wuxi, Jiangsu 214194 China

Made in China

**Active ingredient**

Benzalkonium Chloride, 0.13% w/w

**Purpose**

First Aid Antiseptic

**Use**

First aid antiseptic to help prevent infection in minor cuts, scrapes, and burns

**Warnings**

**For external use only. Do not use**

In the eyes or apply over large areas of the body  
longer than 1 week unless directed by a doctor.

In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.

**Stop use and consult a doctor**

if the condition persists or gets worse.

**Keep out of reach of children.**

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

**Directions**

\* Clean the affected area

\* Apply a small amount of this product on the area 1 to 3 times daily

\* May be covered with a sterile bandage when dry

**Inactive ingredients**

purified water, sodium bicarbonate

50 mm

50 mm

57 mm

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**Lot.No.:**

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**OBSTETRICAL ANTISEPTIC**

benzalkonium chloride swab

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42947-630
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 mL in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42947-630-03	1.4 mL in 1 POUCH		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	01/01/2009	

**Labeler** - Wuxi Medical Instrument Factory (421292863)

**Registrant** - Wuxi Medical Instrument Factory (421292863)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Wuxi Medical Instrument Factory		421292863	manufacture

Revised: 3/2010

Wuxi Medical Instrument Factory