

#### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ALTABAX safely and effectively. See full prescribing information for ALTABAX.

**ALTABAX (retapamulin ointment), 1%**  
**For Dermatological use only**  
**Initial U.S. Approval: 2007**

#### -----INDICATIONS AND USAGE-----

ALTABAX, a pleuromutilin antibacterial, is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* in patients aged 9 months or older. (1)

#### -----DOSAGE AND ADMINISTRATION-----

- Apply a thin layer of ALTABAX to the affected area (up to 100 cm<sup>2</sup> in total area in adults or 2% total body surface area in pediatric patients aged 9 months or older) twice daily for 5 days. (2)
- The treated area may be covered with a sterile bandage or gauze dressing if desired. (2)

#### -----DOSAGE FORMS AND STRENGTHS-----

10 mg retapamulin/1g of ointment in 5, 10, 15, and 30 gram tubes (3)

#### -----CONTRAINDICATIONS-----

None. (4)

#### -----WARNINGS AND PRECAUTIONS-----

- Discontinue in the event of sensitization or severe local irritation. (5.1)
- Not intended for ingestion. Not for intraoral, intranasal, ophthalmic, or intravaginal use. (5.2)

#### -----ADVERSE REACTIONS-----

The most common drug-related adverse reaction was application site irritation (≤2% of patients). (6)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION

Revised: June 2010

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

ALTABAX<sup>®</sup> is indicated for use in adults and pediatric patients aged 9 months and older for the topical treatment of impetigo (up to 100 cm<sup>2</sup> in total area in adults or 2% total body surface area in pediatric patients aged 9 months or older) due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* [see *Clinical Studies* (14)].

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ALTABAX and other antibacterial drugs, ALTABAX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

### **2 DOSAGE AND ADMINISTRATION**

A thin layer of ALTABAX should be applied to the affected area (up to 100 cm<sup>2</sup> in total area in adults or 2% total body surface area in pediatric patients aged 9 months or older) twice daily for 5 days. The treated area may be covered with a sterile bandage or gauze dressing if desired [see *Patient Counseling Information* (17)].

### **3 DOSAGE FORMS AND STRENGTHS**

10 mg retapamulin/1g of ointment in 5, 10, 15, and 30 gram tubes

### **4 CONTRAINDICATIONS**

None.

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1 Local Irritation**

In the event of sensitization or severe local irritation from ALTABAX, usage should be discontinued, the ointment wiped off, and appropriate alternative therapy for the infection instituted [see *Patient Counseling Information* (17)].

#### **5.2 Not for Systemic or Mucosal Use**

ALTABAX is not intended for ingestion or for oral, intranasal, ophthalmic, or intravaginal use. ALTABAX has not been evaluated for use on mucosal surfaces [see *Patient Counseling Information* (17)]. Epistaxis has been reported with the use of ALTABAX on nasal mucosa.

#### **5.3 Potential for Microbial Overgrowth**

The use of antibiotics may promote the selection of nonsusceptible organisms. Should superinfection occur during therapy, appropriate measures should be taken.

Prescribing ALTABAX in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

## 6 ADVERSE REACTIONS

### 6.1 Clinical Studies Experience

The safety profile of ALTABAX was assessed in 2,115 adult and pediatric patients  $\geq 9$  months who used at least one dose from a 5-day, twice a day regimen of retapamulin ointment. Control groups included 819 adult and pediatric patients who used at least one dose of the active control (oral cephalexin), 172 patients who used an active topical comparator (not available in the US), and 71 patients who used placebo.

Adverse events rated by investigators as drug-related occurred in 5.5% (116/2,115) of patients treated with retapamulin ointment, 6.6% (54/819) of patients receiving cephalexin, and 2.8% (2/71) of patients receiving placebo. The most common drug-related adverse events ( $\geq 1\%$  of patients) were application site irritation (1.4%) in the retapamulin group, diarrhea (1.7%) in the cephalexin group, and application site pruritus (1.4%) and application site paresthesia (1.4%) in the placebo group.

Because clinical studies are conducted under varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Adults: The adverse events, regardless of attribution, reported in at least 1% of adults (18 years of age and older) who received ALTABAX are listed in Table 1.

**Table 1. Adverse Events Reported by  $\geq 1\%$  of Adult Patients Treated With ALTABAX in Phase 3 Clinical Studies**

Adverse Event	ALTABAX N = 1,527 %	Cephalexin N = 698 %
Headache	2.0	2.0
Application site irritation	1.6	<1.0
Diarrhea	1.4	2.3
Nausea	1.2	1.9
Nasopharyngitis	1.2	<1.0
Creatinine phosphokinase increased	<1.0	1.0

Pediatrics: The adverse events, regardless of attribution, reported in at least 1% of pediatric patients aged 9 months to 17 years who received ALTABAX are listed in Table 2.

**Table 2. Adverse Events Reported by  $\geq 1\%$  in Pediatric Patients Aged 9 Months to 17 Years Treated With ALTABAX in Phase 3 Clinical Studies**

Adverse Event	ALTABAX N = 588 %	Cephalexin N = 121 %	Placebo N = 64 %
Application site pruritus	1.9	0	0
Diarrhea	1.7	5.0	0
Nasopharyngitis	1.5	1.7	0
Pruritus	1.5	1.0	1.6
Eczema	1.0	0	0
Headache	1.2	1.7	0
Pyrexia	1.2	<1.0	1.6

Other Adverse Events: Application site pain, erythema, and contact dermatitis were reported in less than 1% of patients in clinical studies.

## **7 DRUG INTERACTIONS**

Co-administration of oral ketoconazole 200 mg twice daily increased retapamulin geometric mean AUC<sub>(0-24)</sub> and C<sub>max</sub> by 81% after topical application of retapamulin ointment, 1% on the abraded skin of healthy adult males. Due to low systemic exposure to retapamulin following topical application in patients, dosage adjustments for retapamulin are unnecessary when co-administered with CYP3A4 inhibitors, such as ketoconazole. Based on in vitro P450 inhibition studies and the low systemic exposure observed following topical application of ALTABAX, retapamulin is unlikely to affect the metabolism of other P450 substrates.

The effect of concurrent application of ALTABAX and other topical products to the same area of skin has not been studied.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

Pregnancy Category B

Effects on embryo-fetal development were assessed in pregnant rats given 50, 150, or 450 mg/kg/day by oral gavage on days 6 to 17 postcoitus. Maternal toxicity (decreased body weight gain and food consumption) and developmental toxicity (decreased fetal body weight and delayed skeletal ossification) were evident at doses  $\geq 150$  mg/kg/day. There were no treatment-related malformations observed in fetal rats.

Retapamulin was given as a continuous intravenous infusion to pregnant rabbits at dosages of 2.4, 7.2, or 24 mg/kg/day from day 7 to 19 of gestation. Maternal toxicity (decreased body weight gain, food consumption, and abortions) was demonstrated at dosages  $\geq 7.2$  mg/kg/day (8-fold the estimated maximum achievable human exposure, based on AUC, at 7.2 mg/kg/day). There was no treatment-related effect on embryo-fetal development.

There are no adequate and well-controlled studies in pregnant women. Because animal

reproduction studies are not always predictive of human response, ALTABAX should be used in pregnancy only when the potential benefits outweigh the potential risk.

### **8.3 Nursing Mothers**

It is not known whether retapamulin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ALTABAX is administered to a nursing woman. The safe use of retapamulin during breast-feeding has not been established.

### **8.4 Pediatric Use**

The safety and effectiveness of ALTABAX in the treatment of impetigo have been established in pediatric patients 9 months to 17 years of age. Use of ALTABAX in pediatric patients is supported by evidence from adequate and well-controlled studies of ALTABAX in which 588 pediatric patients received at least one dose of retapamulin ointment, 1% [see *Adverse Reactions (6)*, *Clinical Studies (14)*]. The magnitude of efficacy and the safety profile of ALTABAX in pediatric patients 9 months and older were similar to those in adults.

The safety and effectiveness of ALTABAX in pediatric patients younger than 9 months of age have not been established.

### **8.5 Geriatric Use**

Of the total number of patients in the adequate and well-controlled studies of ALTABAX, 234 patients were 65 years of age and older, of whom 114 patients were 75 years of age and older. No overall differences in effectiveness or safety were observed between these patients and younger adult patients.

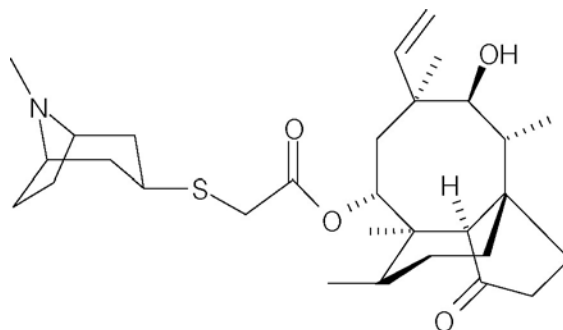
## **10 OVERDOSAGE**

Overdosage with ALTABAX has not been reported. Any signs or symptoms of overdose, either topically or by accidental ingestion, should be treated symptomatically consistent with good clinical practice.

There is no known antidote for overdoses of ALTABAX.

## **11 DESCRIPTION**

ALTABAX contains retapamulin, a semisynthetic pleuromutilin antibiotic. The chemical name of retapamulin is acetic acid, [[(3-*exo*)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl]thio]-, (3a*S*,4*R*,5*S*,6*S*,8*R*,9*R*,9a*R*,10*R*)-6-ethenyldecahydro-5-hydroxy-4,6,9,10-tetramethyl-1-oxo-3a,9-propano-3a*H*-cyclopentacycloocten-8-yl ester. Retapamulin, a white to pale-yellow crystalline solid, has a molecular formula of C<sub>30</sub>H<sub>47</sub>NO<sub>4</sub>S, and a molecular weight of 517.78. The chemical structure is:



Each gram of ointment for dermatological use contains 10 mg of retapamulin in white petrolatum.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

ALTABAX is an antibacterial agent [see *Clinical Pharmacology* (12.4)].

### 12.2 Pharmacodynamics

In post-hoc analyses of manually over-read 12-lead ECGs from healthy subjects (N = 103), no significant effects on QT/QTc intervals were observed after topical application of retapamulin ointment on intact and abraded skin. Due to the low systemic exposure to retapamulin with topical application, QT prolongation in patients is unlikely [see *Clinical Pharmacology* (12.3)].

### 12.3 Pharmacokinetics

**Absorption:** In a study of healthy adult subjects, retapamulin ointment, 1% was applied once daily to intact skin (800 cm<sup>2</sup> surface area) and to abraded skin (200 cm<sup>2</sup> surface area) under occlusion for up to 7 days. Systemic exposure following topical application of retapamulin through intact and abraded skin was low. Three percent of blood samples obtained on Day 1 after topical application to intact skin had measurable retapamulin concentrations (lower limit of quantitation 0.5 ng/mL); thus C<sub>max</sub> values on Day 1 could not be determined. Eighty-two percent of blood samples obtained on Day 7 after topical application to intact skin and 97% and 100% of blood samples obtained after topical application to abraded skin on Days 1 and 7, respectively, had measurable retapamulin concentrations. The median C<sub>max</sub> value in plasma after application to 800 cm<sup>2</sup> of intact skin was 3.5 ng/mL on Day 7 (range 1.2 to 7.8 ng/mL). The median C<sub>max</sub> value in plasma after application to 200 cm<sup>2</sup> of abraded skin was 11.7 ng/mL on Day 1 (range 5.6 to 22.1 ng/mL) and 9.0 ng/mL on Day 7 (range 6.7 to 12.8 ng/mL).

Plasma samples were obtained from 380 adult patients and 136 pediatric patients (aged 2-17 years) who were receiving topical treatment with ALTABAX topically twice daily. Eleven percent had measurable retapamulin concentrations (lower limit of quantitation 0.5 ng/mL), of which the median concentration was 0.8 ng/mL. The maximum measured retapamulin concentration in adults was 10.7 ng/mL and in pediatric patients was 18.5 ng/mL.

**Distribution:** Retapamulin is approximately 94% bound to human plasma proteins, and the protein binding is independent of concentration. The apparent volume of distribution of

retapamulin has not been determined in humans.

**Metabolism:** In vitro studies with human hepatocytes showed that the main routes of metabolism were mono-oxygenation and di-oxygenation. In vitro studies with human liver microsomes demonstrated that retapamulin is extensively metabolized to numerous metabolites, of which the predominant routes of metabolism were mono-oxygenation and N-demethylation. The major enzyme responsible for metabolism of retapamulin in human liver microsomes was cytochrome P450 3A4 (CYP3A4).

**Elimination:** Retapamulin elimination in humans has not been investigated due to low systemic exposure after topical application.

#### **12.4 Microbiology**

Retapamulin is a semisynthetic derivative of the compound pleuromutilin, which is isolated through fermentation from *Clitopilus passeckerianus* (formerly *Pleurotus passeckerianus*). In vitro activity of retapamulin against isolates of *Staphylococcus aureus* as well as *Streptococcus pyogenes* has been demonstrated.

**Antimicrobial Mechanism of Action:** Retapamulin selectively inhibits bacterial protein synthesis by interacting at a site on the 50S subunit of the bacterial ribosome through an interaction that is different from that of other antibiotics. This binding site involves ribosomal protein L3 and is in the region of the ribosomal P site and peptidyl transferase center. By virtue of binding to this site, pleuromutilins inhibit peptidyl transfer, block P-site interactions, and prevent the normal formation of active 50S ribosomal subunits. Retapamulin is bacteriostatic against *Staphylococcus aureus* and *Streptococcus pyogenes* at the retapamulin in vitro minimum inhibitory concentration (MIC) for these organisms. At concentrations 1,000x the in vitro MIC, retapamulin is bactericidal against these same organisms. Retapamulin demonstrates no in vitro target-specific cross-resistance with other classes of antibiotics.

**Mechanisms of Decreased Susceptibility to Retapamulin:** In vitro, 2 mechanisms that cause reduced susceptibility to retapamulin have been identified, specifically, mutations in ribosomal protein L3 or the presence of an efflux mechanism. Decreased susceptibility of *S. aureus* to retapamulin (highest retapamulin MIC was 2 mcg/mL) develops slowly in vitro via multistep mutations in L3 after serial passage in sub-inhibitory concentrations of retapamulin. There was no apparent treatment-associated reduction in susceptibility to retapamulin in the Phase 3 clinical program. The clinical significance of these findings is not known.

**Other:** Based on in vitro broth microdilution susceptibility testing, no differences were observed in susceptibility of *S. aureus* to retapamulin whether the isolates were methicillin-resistant or methicillin-susceptible. Retapamulin susceptibility did not correlate with clinical success rates in patients with methicillin-resistant *S. aureus*. The reason for this is not known but may have been influenced by the presence of particular strains of *S. aureus* possessing certain virulence factors, such as Panton-Valentine Leukocidin (PVL). In the case of treatment failure associated with *S. aureus* (regardless of methicillin susceptibility), the presence of strains possessing additional virulence factors (such as PVL) should be considered.

Retapamulin has been shown to be active against the following microorganisms, both in



196 vitro and in clinical trials [see *Indications and Usage (1)*].

197 ***Aerobic and Facultative Gram-Positive Bacteria:***

198 *Staphylococcus aureus* (methicillin-susceptible isolates only)

199 *Streptococcus pyogenes*

200 **Susceptibility Testing:** The clinical microbiology laboratory should provide cumulative  
201 results of the in vitro susceptibility test results for antimicrobial drugs used in local hospitals and  
202 practice areas to the physician as periodic reports that describe the susceptibility profile of  
203 nosocomial and community-acquired pathogens. These reports should aid the physician in  
204 selecting the most effective antimicrobial.

205 ***Susceptibility Testing Techniques:***

206 ***Dilution Techniques:*** Quantitative methods can be used to determine the  
207 minimum inhibitory concentration (MIC) of retapamulin that will inhibit the growth of the  
208 bacteria being tested. The MIC provides an estimate of the susceptibility of bacteria to  
209 retapamulin. The MIC should be determined using a standardized procedure.<sup>1,2</sup> Standardized  
210 procedures are based on a dilution method (broth or agar) or equivalent with standardized  
211 inoculum concentrations and standardized concentrations of retapamulin powder.

212 ***Diffusion Techniques:*** Quantitative methods that require measurement of zone  
213 diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial  
214 compounds. One such standardized procedure requires the use of standardized inoculum  
215 concentrations.<sup>2,3</sup> This procedure uses paper disks impregnated with 2 mcg of retapamulin to test  
216 the susceptibility of microorganisms to retapamulin.

217 ***Susceptibility Test Interpretive Criteria:*** In vitro susceptibility test interpretive criteria  
218 for retapamulin have not been determined for this topical antimicrobial. The relation of the in  
219 vitro MIC and/or disk diffusion susceptibility test results to clinical efficacy of retapamulin  
220 against the bacteria tested should be monitored.

221 ***Quality Control Parameters for Susceptibility Testing:*** In vitro susceptibility test  
222 quality control parameters were developed for retapamulin so that laboratories that test the  
223 susceptibility of bacterial isolates to retapamulin can determine if the susceptibility test is  
224 performing correctly. Standardized dilution techniques and diffusion methods require the use of  
225 laboratory control microorganisms to monitor the technical aspects of the laboratory procedures.  
226 Standard retapamulin powder should provide the following MIC and a 2 mcg retapamulin disk  
227 should produce the following zone diameters with the indicated quality control strains in Table 3.



**Table 3. Acceptable Quality Control Ranges for Retapamulin**

Microorganism	MIC Range (mcg/mL)	Disk Diffusion Zone Diameter (mm)
<i>Staphylococcus aureus</i> ATCC 29213	0.06-0.25	NA
<i>Staphylococcus aureus</i> ATCC 25923	NA	23-30
<i>Streptococcus pneumoniae</i> ATCC 49619	0.06-0.5 <sup>a</sup>	13-19 <sup>b</sup>

NA = Not applicable.

<sup>a</sup> This quality control range is applicable using cation-adjusted Mueller-Hinton broth with 2-5% lysed horse blood.

<sup>b</sup> This quality control limit is applicable using Mueller-Hinton agar with 5% sheep blood.

### **13 NONCLINICAL TOXICOLOGY**

#### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to evaluate carcinogenic potential have not been conducted with retapamulin.

Retapamulin showed no genotoxicity when evaluated in vitro for gene mutation and/or chromosomal effects in the mouse lymphoma cell assay, in cultured human peripheral blood lymphocytes, or when evaluated in vivo in a rat micronucleus test.

No evidence of impaired fertility was found in male or female rats given retapamulin 50, 150, or 450 mg/kg/day orally.

### **14 CLINICAL STUDIES**

ALTABAX was evaluated in a placebo-controlled study that enrolled adult and pediatric patients 9 months of age and older for treatment of impetigo up to 100 cm<sup>2</sup> in total area (up to 10 lesions) or a total body surface area not exceeding 2%. The majority of patients enrolled (164/210, 78%) were under the age of 13. The study was a double-blind, randomized, multi-center, parallel-group comparison of the safety of ALTABAX and placebo ointment, both applied twice daily for 5 days. The study was randomized 2 ALTABAX to 1 placebo patient. Patients with underlying skin disease (e.g., preexisting eczematous dermatitis) or skin trauma, with clinical evidence of secondary infection were excluded from these studies. In addition, patients with any systemic signs and symptoms of infection (such as fever) were excluded from the study. Clinical success was defined as the absence of treated lesions, or treated lesions had become dry without crusts with or without erythema compared to baseline, or had improved (defined as a decline in the size of the affected area, number of lesions or both) such that no further antimicrobial therapy was required. The intent-to-treat clinical (ITTC) population consisted of all randomized patients who took at least 1 dose of study medication. The clinical per protocol (PPC) population included all ITTC patients who satisfied the inclusion/exclusion criteria and subsequently adhered to the protocol. The intent-to-treat bacteriological (ITTb) population consisted of all randomized patients who took at least one dose of study medication

and had a pathogen identified at study entry. The bacteriological per protocol (PPB) population included all ITTB patients who satisfied the inclusion/exclusion criteria and subsequently adhered to the protocol.

The following table describes the results for clinical response at end of therapy (2 days after treatment) and follow-up (9 days after treatment), by analysis population:

**Table 4. Clinical Response at End of Therapy and at Follow-Up by Analysis Population**

Analysis Population	ALTABAX		Placebo		Difference in Success Rates (%)	95% CI (%)
	n/N	Success Rate (%)	n/N	Success Rate (%)		
End of Therapy						
PPC	111/124	89.5	33/62	53.2	36.3	(22.8, 49.8)
ITTC	119/139	85.6	37/71	52.1	33.5	(20.5, 46.5)
PPB	96/107	89.7	26/52	50.0	39.7	(25.0, 54.5)
ITTB	101/114	88.6	28/57	49.1	39.5	(25.2, 53.7)
Follow-Up						
PPC	98/119	82.4	25/58	43.1	39.2	(24.8, 53.7)
ITTC	105/139	75.5	28/71	39.4	36.1	(22.7, 49.5)
PPB	86/102	84.3	18/48	37.5	46.8	(31.4, 62.2)
ITTB	91/114	79.8	19/57	33.3	46.5	(32.2, 60.8)

n = number with clinical success outcome, N = number in analysis population, PPC = Clinical Per Protocol Population, ITTC = Clinical Intent to Treat Population, PPB = Bacteriological Per Protocol Population, ITTB = Bacteriological Intent to Treat Population

The following table describes the clinical success at end of therapy and follow-up by baseline pathogen:

**Table 5. Clinical Response at End of Therapy and Follow-Up for Patients With *Staphylococcus aureus* and *Streptococcus pyogenes* at Baseline in the Per Protocol Bacteriological Population (PPB)**

Pathogen	ALTABAX		Placebo	
	n/N	Success Rate (%)	n/N	Success Rate (%)
End of Therapy				
<i>Staphylococcus aureus</i> (Methicillin-susceptible)	79/88	89.8	25/48	52.1
<i>Streptococcus pyogenes</i>	29/32	90.6	3/7	42.9
Follow-Up				
<i>Staphylococcus aureus</i> (Methicillin-susceptible)	71/84	84.5	19/44	43.2
<i>Streptococcus pyogenes</i>	29/32	90.6	2/6	33.3

n/N = number of clinical successes/number of pathogens isolated at baseline.

Examination of age and gender subgroups did not identify differences in response to ALTABAX among these groups. The majority of patients entered into this study were classified as White/Caucasian or of Asian heritage; when response rates by racial subgroups were viewed across studies, differences in response to ALTABAX were not identified.

## 15 REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI) Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. Approved Standard. CLSI Document M7-A7. CLSI, Wayne, PA, Jan. 2006.
2. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing – 17<sup>th</sup> Informational Standard. M100-S17. CLSI, Wayne, PA, Jan. 2007.
3. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Disk Susceptibility Tests. Approved Standard. CLSI Document M2-A9. CLSI, Wayne, PA, Jan. 2006.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

ALTABAX is supplied in 5 gram, 10 gram, 15 gram and 30 gram tubes.  
NDC 0007-5180-05 (5 gram tube)  
NDC 0007-5180-10 (10 gram tube)  
NDC 0007-5180-22 (15 gram tube)  
NDC 0007-5180-25 (30 gram tube)  
Store at 25°C (77°F) with excursions permitted to 15°-30°C (59°-86°F).

## 17 PATIENT COUNSELING INFORMATION

Patients using ALTABAX and/or their guardians should receive the following information and instructions:

- Use ALTABAX as directed by the healthcare practitioner. As with any topical medication, patients and caregivers should wash their hands after application if the hands are not the area for treatment.
- ALTABAX is for external use only. Do not swallow ALTABAX or use it in the eyes, on the mouth or lips, inside the nose, or inside the female genital area.
- The treated area may be covered by a sterile bandage or gauze dressing, if desired. This may also be helpful for infants and young children who accidentally touch or lick the lesion site. A bandage will protect the treated area and avoid accidental transfer of ointment to the eyes or other areas.
- Use the medication for the full time recommended by the healthcare practitioner, even though symptoms may have improved.
- Notify the healthcare practitioner if there is no improvement in symptoms within 3 to 4 days after starting use of ALTABAX.
- ALTABAX may cause reactions at the site of application of the ointment. Inform the healthcare practitioner if the area of application worsens in irritation, redness, itching, burning, swelling, blistering, or oozing.

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GlaxoSmithKline

Research Triangle Park, NC 27709

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