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) Safety in patients younger than 9 months has not been established.

---------- DOSAGE AND ADMINISTRATION ----------
- Apply a thin layer of ALTABAX to the affected area (up to 100 cm^2 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 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.

See 17 for PATIENT COUNSELING INFORMATION

Revised: December 2012

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.**

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ALTABAX® is indicated for use in adults and pediatric patients aged 9 months and older for the topical treatment of impetigo (up to 100 cm^2 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)]*. Safety in patients younger than 9 months has not been established.

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^2 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)]*.

Reference ID: 3236062

3 DOSAGE FORMS AND STRENGTHS

10 mg retapamulin/1g of ointment in 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. The efficacy and safety of ALTABAX on mucosal surfaces have not been established. 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

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.

The safety profile of ALTABAX was assessed in 2,115 adult and pediatric patients ≥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 (≥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.

Adults: The adverse events, regardless of attribution, reported in at least 1% of adults

(18 years of age and older) who received ALTABAX or comparator are presented in Table 1.

Table 1. Adverse Events Reported by ≥1% of Adult Patients Treated With ALTABAX or Comparator 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 presented in Table 2.

Table 2. Adverse Events Reported by ≥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.

6.2 Postmarketing Experience

In addition to reports in clinical trials, the following events have been identified during postmarketing use of ALTABAX. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General Disorders and Administration Site Conditions: Application site burning.

Immune System Disorders: Hypersensitivity including angioedema.

7 DRUG INTERACTIONS

Coadministration of oral ketoconazole 200 mg twice daily increased retapamulin

geometric mean $AUC_{(0-24)}$ and C_{max} 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 adults and pediatric patients 2 years of age and older, dosage adjustments for retapamulin are unnecessary in these patients when coadministered 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.

Concomitant administration of retapamulin and CYP3A4 inhibitors, such as ketoconazole, has not been studied in pediatric patients. In pediatric patients 2 to 24 months of age, systemic exposure of retapamulin was higher compared with patients ≥2 years of age after topical application *[see Pharmacokinetics (12.3)]*. Based on the higher exposure of retapamulin, it is not recommended to coadminister ALTABAX with strong CYP3A4 inhibitors in patients younger than 24 months of age.

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 ≥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 ≥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 (9 months to 17 years of age) 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 (6.1), 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. An open-label clinical study of topical treatment with ALTABAX (twice daily for 5 days) was conducted in patients 2 to 24 months of age. Plasma samples were obtained from 79 patients. In these pediatric patients, systemic exposure of retapamulin was higher compared with patients 2 to 17 years of age. Furthermore, a higher proportion of pediatric patients 2 to 9 months of age had measurable concentrations (>0.5 ng/mL) of retapamulin compared with patients 9 to 24 months of age *[see Pharmacokinetics (12.3)]*. The highest levels were seen in patients 2 to 6 months of age *[see Pharmacokinetics (12.3)]*. The use of retapamulin is not indicated in pediatric patients younger than 9 months of age.

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.

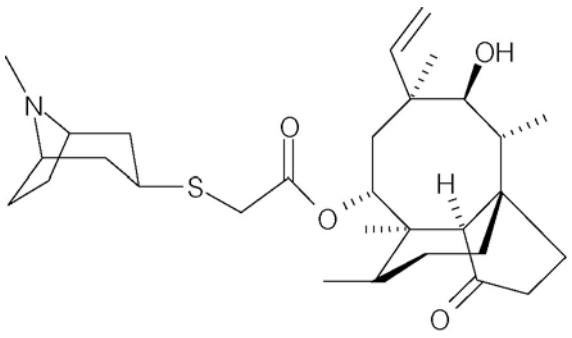
10 OVERDOSAGE

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 $C_{30}H_{47}NO_4S$, 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^2 surface area) and to abraded skin (200 cm^2 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_{max} 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_{max} value in plasma after application to 800 cm^2 of intact skin was 3.5 ng/mL on Day 7 (range 1.2 to 7.8 ng/mL). The median C_{max} value in plasma after application to 200 cm^2 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 to 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 (aged 2 to 17 years) was 18.5 ng/mL.

A single plasma sample was obtained from 79 pediatric patients (aged 2 to 24 months) who were receiving topical treatment with ALTABAX twice daily. Forty-six percent had measurable retapamulin concentrations (> 0.5 ng/mL) compared with 7% in pediatric patients 2 to 17 years of age. A higher proportion (69%) of pediatric patients aged 2 to 9 months had measurable concentrations of retapamulin compared with patients aged 9 to 24 months (32%). Among pediatric patients 2 to 9 months of age (n = 29), four patients had retapamulin concentrations that were higher (≥26.9 ng/mL) than the maximum concentration observed in pediatric patients aged 2 to 17 years (18.5 ng/mL). Among pediatric patients aged 9 to 24 months

(n = 50), one patient had a retapamulin concentration that was higher (95.1 ng/mL) than the maximum level observed in pediatric patients aged 2 to 17 years.

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. Although cross-resistance between retapamulin and other antibacterial classes (such as clindamycin and oxazolidones) exist, isolates resistant to these classes may be susceptible to retapamulin.

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, the presence of Cfr rRNA methyltransferase 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 vitro and in clinical trials *[see Indications and Usage (1)]*.

Aerobic and Facultative Gram-Positive Bacteria:

Staphylococcus aureus (methicillin-susceptible isolates only)

Streptococcus pyogenes

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

Susceptibility Testing Techniques:

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

Diffusion Techniques: Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure requires the use of standardized inoculum concentrations.[2,3] This procedure uses paper disks impregnated with 2 mcg of retapamulin to test the susceptibility of microorganisms to retapamulin.

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

Quality Control Parameters for Susceptibility Testing: In vitro susceptibility test quality control parameters were developed for retapamulin so that laboratories that test the susceptibility of bacterial isolates to retapamulin can determine if the susceptibility test is performing correctly. Standardized dilution techniques and diffusion methods require the use of laboratory control microorganisms to monitor the technical aspects of the laboratory procedures. Standard retapamulin powder should provide the following MIC and a 2 mcg retapamulin disk 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)
Staphylococcus aureus ATCC 29213	0.06-0.25	NA
Staphylococcus aureus ATCC 25923	NA	23-30
Streptococcus pneumoniae ATCC 49619	0.06-0.5[a]	13-19[b]

NA = Not applicable.

[a] This quality control range is applicable using cation-adjusted Mueller-Hinton broth with 2-5% lysed horse blood.

[b] 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^2 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. Patients were randomized to ALTABAX or placebo (2:1). 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.

Table 4 presents 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

Table 5 presents the clinical success at end of therapy and follow-up by baseline pathogen.

Reference ID: 3236062

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)

	ALTABAX		Placebo	
Pathogen	**n/N**	**Success Rate (%)**	**n/N**	**Success Rate (%)**
End of Therapy				
Staphylococcus aureus (Methicillin-susceptible)	79/88	89.8	25/48	52.1
Streptococcus pyogenes	29/32	90.6	3/7	42.9
Follow-Up				
Staphylococcus aureus (Methicillin-susceptible)	71/84	84.5	19/44	43.2
Streptococcus pyogenes	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-Eighth Edition. CLSI Document M07-A9, Vol. 32, No. 2. CLSI, Wayne, PA, Jan. 2012.
2. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing: Nineteenth Informational Supplement. CLSI Document M100-S22. Vol. 32, No. 3. CLSI, Wayne, PA, Jan. 2012.
3. Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Disk Susceptibility Tests. Approved Standard-Tenth Edition. CLSI Document M02-A11, Vol. 32, No. 1. CLSI, Wayne, PA, Jan. 2012.

16 HOW SUPPLIED/STORAGE AND HANDLING

ALTABAX is supplied in 15-gram and 30-gram tubes.

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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ALX:4PI