

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208744Orig1s000

CLINICAL MICROBIOLOGY/VIROLOGY
REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: January 16, 2018

THROUGH: Kerian Grande Roche, PhD, Clinical Microbiology Reviewer, DAIP
Avery Goodwin, PhD, Acting Clinical Microbiology Team Leader, DAIP

FROM: Katherine Schumann, Associate Director for Regulatory Affairs, OAP

SUBJECT: Clinical Microbiology Labeling Changes Required by Section 511A of the Food, Drug and Cosmetic Act (FD&C Act)

APPLICATION/DRUG: NDA 208744, tigecycline for injection, 50 mg/vial

Section 511A of the FD&C Act required FDA to establish a Susceptibility Test Interpretive Criteria web page within one year of enactment of the 21st Century Cures Act. It also requires that all antimicrobial drugs approved on or after the date of establishment of the Interpretive Criteria web page include in labeling a reference to the Interpretive Criteria web page in lieu of susceptibility test interpretive criteria (breakpoints) and related information.

The clinical microbiology review dated November 25, 2017 and signed in DARRTS January 09, 2018 for the Class 2 resubmission for this 505(b)(2) NDA addresses the (b) (4)

As explained in the December 2017 final guidance, *Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretive Criteria Labeling for NDAs and ANDAs*, the labeling for this drug is required to include a reference to the Interpretive Criteria web page (b) (4) if the application is approved it will be after the date of the establishment of the Interpretive Criteria web page. In addition, (b) (4)

Proposed changes to labeling are shown below in track changes and should be communicated to the applicant:

12.4 (b) (4) Microbiology

Susceptibility Test (b) (4) -ing

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: <https://www.fda.gov/STIC>.

(b) (4)

2 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS)
immediately following this page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHERINE SCHUMANN
01/16/2018

DIVISION OF ANTI-INFECTIVE PRODUCTS
CLINICAL MICROBIOLOGY REVIEW
Date review completed: 11-25-17

NDA 208744 Tigecycline for Injection, USP 50 mg/vial

Date Company Submitted Document: 7-18-17
Received for Review: 7-18-17
Date Assigned: 7-18-17

CDER Date Received: 7-18-17
Reviewer: Kerian Grande Roche

NAME AND ADDRESS OF Applicant

Accord Healthcare Inc.
1009 Slater Road,
Suite 210-B
Durham NC 27703, USA

CONTACT PERSON

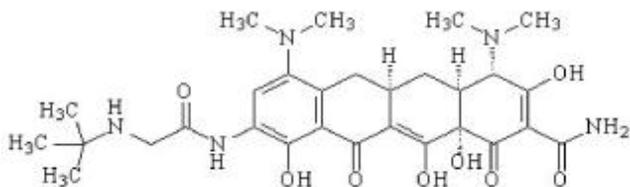
Sabita Nair
Sr. Director-Regulatory Affairs

DRUG PRODUCT NAME

Proprietary Name: N/A

Established Name/Code Name(s): Tigecycline for Injection, USP 50 mg/vial

Chemical Name: (4*S*,4*aS*,5*aR*,12*aS*)-9-[2-(*tert*-butylamino)acetamido]-4,7-bis(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,10,12,12*a*-tetrahydroxy-1,11-dioxo-2naphthacencarboxamide
Chemical Structure:



DRUG CATEGORY:

Antibiotic

PROPOSED INDICATION(S)

Tigecycline for injection USP is a tetracycline-class antibacterial drug indicated in patients 18 years of age and older for:

- Complicated skin and skin structure infections
- Complicated intra-abdominal infections
- Community-acquired bacterial pneumonia

PROPOSED DOSAGE FORM, DOSAGE, ROUTE OF ADMINISTRATION, STRENGTH AND DURATION OF TREATMENT

Dosage Form: lyophilized powder for reconstitution

Route of Administration: Intravenous

DIVISION OF ANTI-INFECTIVE PRODUCTS

CLINICAL MICROBIOLOGY REVIEW

Date review completed: 11-25-17

NDA 208744 Tigecycline for Injection, USP 50 mg/vial

Dosage: Initial dose of 100 mg, followed by 50 mg every 12 hours administered intravenously over approximately 30 to 60 minutes.

Strength: 50 mg/vial

Duration of Treatment: The recommended duration of treatment with tigecycline for injection for complicated skin and skin structure infections or for complicated intra-abdominal infections is 5 to 14 days. The recommended duration of treatment with tigecycline for injection for community-acquired bacterial pneumonia is 7 to 14 days.

DISPENSED:

Rx

RELATED DOCUMENTS:

NDA 21821 Tygacil

REMARKS

This is a class 2 resubmission for a 505(b)(2) NDA for tigecycline for injection, USP 50 mg/vial. This 505(b)(2) relies on the Agency's findings of safety and effectiveness for the reference listed drug, Tygacil (tigecycline) for injection (NDA 21821) as reflected in the approved labeling.

CONCLUSIONS AND RECOMMENDATIONS

From a Clinical Microbiology standpoint, this application may be approved as the Applicant has agreed to the Agency's recommended labeling changes as indicated below:

-
-
-



Kerian Grande Roche, PhD.
Clinical Microbiology Reviewer

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KERIAN K GRANDE ROCHE
01/05/2018

AVERY C GOODWIN
01/09/2018

DIVISION OF ANTI-INFECTIVE PRODUCTS
CLINICAL MICROBIOLOGY REVIEW
Date review completed: 6-21-16

NDA 208744 Tigecycline for Injection, USP 50 mg/vial

Date Company Submitted Document: 11-30-15
Received for Review: 11-30-15
Date Assigned: 11-30-15

CDER Date Received: 11-30-15
Reviewer: Kerian Grande Roche

NAME AND ADDRESS OF Applicant

Accord Healthcare Inc.
1009 Slater Road,
Suite 210-B
Durham NC 27703, USA

CONTACT PERSON

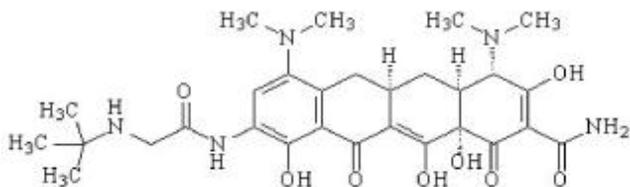
Sabita Nair
Sr. Director-Regulatory Affairs

DRUG PRODUCT NAME

Proprietary Name: N/A

Established Name/Code Name(s): Tigecycline for Injection, USP 50 mg/vial

Chemical Name: (4*S*,4*aS*,5*aR*,12*aS*)-9-[2-(*tert*-butylamino)acetamido]-4,7-bis(dimethylamino)-1,4,4*a*,5,5*a*,6,11,12*a*-octahydro-3,10,12,12*a*-tetrahydroxy-1,11-dioxo-2naphthacencarboxamide
Chemical Structure:



DRUG CATEGORY:

Antibiotic

PROPOSED INDICATION(S)

Tigecycline for injection USP is a tetracycline-class antibacterial drug indicated in patients 18 years of age and older for:

- Complicated skin and skin structure infections
- Complicated intra-abdominal infections
- Community-acquired bacterial pneumonia

PROPOSED DOSAGE FORM, DOSAGE, ROUTE OF ADMINISTRATION, STRENGTH AND DURATION OF TREATMENT

Dosage Form: lyophilized powder for reconstitution

Route of Administration: Intravenous

DIVISION OF ANTI-INFECTIVE PRODUCTS

CLINICAL MICROBIOLOGY REVIEW

Date review completed: 6-21-16

NDA 208744 Tigecycline for Injection, USP 50 mg/vial

Dosage: Initial dose of 100 mg, followed by 50 mg every 12 hours administered intravenously over approximately 30 to 60 minutes.

Strength: 50 mg/vial

Duration of Treatment: The recommended duration of treatment with tigecycline for injection for complicated skin and skin structure infections or for complicated intra-abdominal infections is 5 to 14 days. The recommended duration of treatment with tigecycline for injection for community-acquired bacterial pneumonia is 7 to 14 days.

DISPENSED:

Rx

RELATED DOCUMENTS:

NDA 21821 Tygacil

REMARKS

The company submitted a 505(b)(2) NDA for tigecycline for injection, USP 50 mg/vial on Sept. 30, 2015. This 505(b)(2) relies on the Agency's findings of safety and effectiveness for the reference listed drug, Tygacil (tigecycline) for injection (NDA 21821) as reflected in the approved labeling.

CONCLUSIONS AND RECOMMENDATIONS

From a Clinical Microbiology standpoint this application may be approved with the recommended labeling changes as indicated below:

-

-

(b) (4)

Kerian Grande Roche, PhD.
Clinical Microbiology Reviewer
6-21-16

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KERIAN K GRANDE ROCHE
06/23/2016

KALAVATI C SUVARNA
06/23/2016