

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**213433Orig1s000**

**MULTI-DISCIPLINE REVIEW**

**Summary Review**

**Clinical Review**

**Non-Clinical Review**

**Statistical Review**

**Clinical Pharmacology Review**

### NDA Multidisciplinary Review and Evaluation

<b>Application Type</b>	NME- In "The Program"
<b>Application Number(s)</b>	NDA 213433
<b>Priority or Standard</b>	Standard
<b>Submit Date(s)</b>	August 19, 2019
<b>Received Date(s)</b>	August 27, 2019
<b>PDUFA Goal Date</b>	August 27, 2020
<b>Division/Office</b>	Shari Targum, Deputy Director, Division of Dermatology and Dentistry Julie Beitz, Director Office of Immunology and Inflammation
<b>Review Completion Date</b>	
<b>Established/Proper Name</b>	Clascoterone cream, 1%
<b>(Proposed) Trade Name</b>	WINLEVI
<b>Pharmacologic Class</b>	NME
<b>Code Name</b>	N/A
<b>Applicant</b>	Cassiopea SpA
<b>Dosage Form</b>	Topical cream
<b>Applicant proposed Dosing Regimen</b>	Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening)
<b>Applicant Proposed Indication(s)/Population(s)</b>	For the treatment of acne vulgaris in patients 9 years of age and older
<b>Applicant Proposed SNOMED CT Indication Disease Term for Each Proposed Indication</b>	
<b>Recommendation on Regulatory Action</b>	Approval
<b>Recommended Indication(s)/Population(s) (if applicable)</b>	For the treatment of acne vulgaris in patients 12 years of age and older
<b>Recommended SNOMED CT Indication Disease Term for Each Indication (if applicable)</b>	
<b>Recommended Dosing Regimen</b>	Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening).

## Table of Contents

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Table of Contents .....	i
Table of Tables .....	1
Table of Figures.....	5
Reviewers of Multidisciplinary Review and Evaluation .....	6
Glossary .....	9
1. Executive Summary.....	11
1.1. Product Introduction .....	11
1.2. Conclusions on Substantial Evidence of Effectiveness .....	11
1.3. Benefit-Risk Assessment .....	12
1.4. Patient Experience Data .....	15
2. Therapeutic Context .....	16
2.1. Analysis of Condition .....	16
2.2. Analysis of Current Treatment Options.....	18
3. Regulatory Background.....	26
3.1. U.S. Regulatory Actions and Marketing History .....	26
3.2. Summary of Presubmission/Submission Regulatory Activity.....	26
4. Significant Issues From Other Review Disciplines Pertinent to Clinical Conclusions on Efficacy and Safety .....	27
4.1. Office of Scientific Investigations .....	27
4.2. Product Quality .....	28
4.2.1. Drug Substance .....	28
4.2.2. Drug Product.....	28
4.2.3. OPQ Recommendation .....	29
5. Nonclinical Pharmacology/Toxicology .....	29
5.1. Executive Summary .....	29
5.2. Referenced NDAs, BLAs, DMFs.....	31
5.3. Pharmacology.....	31
5.3.1. Safety Pharmacology .....	32
5.4. ADME/PK.....	33
5.5. Toxicology.....	34
5.5.1. General Toxicology .....	34
5.5.2. Genetic Toxicology.....	37
5.5.3. Carcinogenicity .....	38

N Multidisciplinary Review and Evaluation: NDA 213433  
WINLEVI (clascoterone) cream, 1%

5.5.4. Reproductive and Developmental Toxicology .....	39
5.5.5. Other Toxicology Studies .....	43
6. Clinical Pharmacology .....	44
6.1. Executive Summary .....	44
6.1.1. Recommendations .....	45
6.1.2. Postmarketing Requirements and Commitment .....	45
6.2. Summary of Clinical Pharmacology Assessment .....	45
6.2.1. Pharmacology and Clinical Pharmacokinetics.....	45
6.2.2. General Dosing and Therapeutic Individualization .....	47
6.2.3. Outstanding Issues.....	47
6.3. Comprehensive Clinical Pharmacology Review .....	48
6.3.1. General Pharmacology and Pharmacokinetic Characteristics .....	48
6.3.2. Clinical Pharmacology Questions .....	49
7. Sources of Clinical Data and Review Strategy .....	51
7.1. Table of Clinical Studies.....	51
7.2. Review Strategy.....	55
7.2.1. Data Sources .....	55
7.2.2. Data and Analysis Quality .....	55
8. Statistical and Clinical Evaluation.....	55
8.1. Review of Relevant Individual Trials Used to Support Efficacy .....	55
8.1.1. Study Design and Endpoints .....	55
8.1.2. Statistical Methodologies .....	56
8.1.3. Subject Disposition, Demographics, and Baseline Disease Characteristics .....	57
8.1.4. Results of Coprimary Efficacy Endpoints .....	59
8.1.5. Results of Secondary Efficacy Endpoints .....	62
8.1.6. Efficacy Results in Subjects $\geq 12$ Years of Age .....	62
8.1.7. Findings in Special/Subgroup Populations.....	64
8.2. Review of Safety .....	74
8.2.1. Safety Review Approach .....	74
8.2.2. Review of Safety Database .....	75
8.2.3. Adequacy of Applicant's Clinical Safety Assessments.....	79
8.2.4. Safety Results.....	81
8.2.5. Analysis of Submission-Specific Safety Issues.....	95
8.2.6. Clinical Outcome Assessment Analyses Informing Safety/Tolerability.....	103
8.2.7. Safety Analyses by Demographic Subgroups .....	103

N Multidisciplinary Review and Evaluation: NDA 213433

WINLEVI (clascoterone) cream, 1%

8.2.8. Specific Safety Studies/Clinical Trials.....	103
8.2.9. Additional Safety Explorations.....	106
8.2.10. Safety in the Postmarket Setting.....	109
8.2.11. Integrated Assessment of Safety.....	109
8.3. Summary and Conclusions.....	110
8.3.1. Statistical Issues.....	110
8.3.2. Conclusions and Recommendations.....	111
9. Advisory Committee Meeting and Other External Consultations.....	112
10. Pediatrics.....	112
11. Labeling Recommendations.....	112
11.1. Prescription Drug Labeling.....	112
12. Risk Evaluation and Mitigation Strategies.....	113
13. Postmarketing Requirements and Commitment.....	114
14. Division Director (OCP) Comments.....	115
15. Division Director (OB) Comments.....	115
16. Division Director (Clinical) Comments.....	115
17. Office Director (or Designated Signatory Authority) Comments.....	116
18. Appendices.....	117
18.1. References.....	117
18.2. Clinical Assessments.....	118
18.3. Clinical Pharmacology Assessments.....	120
18.3.1. Summary of Bioanalytical Method Validation and Performance.....	120
18.3.2. Clinical Pharmacology Studies.....	123
18.3.3. Studies Using Human Biomaterials.....	133
18.4. Financial Disclosure.....	138
18.5. Nonclinical Pharmacology/Toxicology.....	139
18.5.1. Calculations for Multiples of Exposures.....	139
18.5.2. Nonclinical Labeling.....	140
18.5.3. Review of Carcinogenicity Study Conducted With Clascoterone.....	144

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