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APPLICATION NUMBER:

204427Orig1s000

MEDICAL REVIEW(S)



CLINICAL REVIEW

Application Type NDA
Application Number 204,427
Priority or Standard Standard

Submit Date July 29, 2013 Received Date July 29, 2013 PDUFA Goal Date July 29, 2014 Division / Office DDDP

Reviewer Name Milena Lolic, M.D., M.S. Review Completion Date March 11, 2014

Established Name Tavaborole solution 5%
Trade Name Kerydin
Therapeutic Class Oxaborole antifungal
Applicant Anacor Pharmaceuticals Inc.

Formulation Solution
Dosing Regimen Daily for 48 weeks
Indication Onychomycosis
Intended Population Adults

Template Version: March 6, 2009



Clinical Review Milena Lolic, MD, MS NDA 204,427 Kerydin (tavaborole) Topical Solution, 5%

Table of Contents

1	RE	COMMENDATIONS/RISK BENEFIT ASSESSMENT	7
	1.1 1.2 1.3 1.4	Recommendation on Regulatory Action	7 8 8
2	INT	RODUCTION AND REGULATORY BACKGROUND	9
	2.1 2.2 2.3 2.4 2.5 2.6	Product Information	10 12 12 12
3	ETI	HICS AND GOOD CLINICAL PRACTICES	13
	3.1 3.2 3.3	Submission Quality and Integrity Compliance with Good Clinical Practices Financial Disclosures	13
4		SNIFICANT EFFICACY/SAFETY ISSUES RELATED TO OTHER REVIEW SCIPLINES	28
	4.1 4.2 4.3 4.4 4.4	,	29 33 34 35
5	so	URCES OF CLINICAL DATA	38
	5.1 5.2 5.3	Tables of Studies/Clinical Trials	39
6	RE'	VIEW OF EFFICACY	48
	Effica 6.1 6.1 6.1 6.1 6.1 6.1	.1 Methods	49 50 51 52 53
	0.1	Other Endpoints	J



Clinical Review Milena Lolic, MD, MS NDA 204,427 Kerydin (tavaborole) Topical Solution, 5%

	6.1.7	Subpopulations	
	6.1.8	Analysis of Clinical Information Relevant to Dosing Recommendations	
	6.1.9	Discussion of Persistence of Efficacy and/or Tolerance Effects	
	6.1.10	Additional Efficacy Issues/Analyses	. 57
7	REVIE\	W OF SAFETY	. 59
	Safety Su	ummary	. 59
		thodsthods	
	7.1.1	Studies/Clinical Trials Used to Evaluate Safety	. 60
	7.1.2	Categorization of Adverse Events	
	7.1.3	Pooling of Data Across Studies/Clinical Trials to Estimate and Compare	
		Incidence	. 63
		equacy of Safety Assessments	. 63
	7.2.1	Overall Exposure at Appropriate Doses/Durations and Demographics of	
		Target Populations	
	7.2.2	Explorations for Dose Response	
	•	AN2690-ONYC-200/200A	
	7.2.3	Special Animal and/or In Vitro Testing	
	7.2.4	Routine Clinical Testing	
	7.2.5	Metabolic, Clearance, and Interaction Workup	
	7.2.6	Evaluation for Potential Adverse Events for Similar Drugs in Drug Class	
	7.3 Maj	jor Safety Results Deaths	
	7.3.1	Nonfatal Serious Adverse Events	
	7.3.2	Dropouts and/or Discontinuations	
	7.3.4	Significant Adverse Events	
	7.3.5	Submission Specific Primary Safety Concerns	
		oportive Safety Results	
	7.4.1	Common Adverse Events	
	7.4.2	Laboratory Findings	
	7.4.3	Vital Signs	
	7.4.4	Electrocardiograms (ECGs)	
	7.4.5	Special Safety Studies/Clinical Trials	. 84
	7.4.6	Immunogenicity	. 87
	7.5 Oth	ner Safety Explorations	
	7.5.1	Dose Dependency for Adverse Events	
	7.5.2	Time Dependency for Adverse Events	
	7.5.3	Drug-Demographic Interactions	
	7.5.4	Drug-Disease Interactions	
	7.5.5	Drug-Drug Interactions	
		ditional Safety Evaluations	
	7.6.1	Human Carcinogenicity	
	7.6.2	Human Reproduction and Pregnancy Data	
	7.6.3	Pediatrics and Assessment of Effects on Growth	. ಆತ



Clinical Review Milena Lolic, MD, MS NDA 204,427 Kerydin (tavaborole) Topical Solution, 5%

	6.4 Overdose, Drug Abuse Potential, Withdrawal and Rebound	
7.7	Additional Submissions / Safety Issues	95
8 PC	DSTMARKET EXPERIENCE	95
9 AF	PPENDICES	96
9.1	Literature Review/References	96
9.2	Labeling Recommendations	96
9.3	Advisory Committee Meeting	96
9.4.	Clinical Investigator Financial Disclosure	96



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