CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213422Orig1s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

Date of This Memorandum:	June 4, 2020
Requesting Office or Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	NDA 213422
Product Name and Strength:	(calcipotriene/betamethasone dipropionate) cream, 0.005%/0.064%
Applicant/Sponsor Name:	MC2 Therapeutics Ltd
OSE RCM #:	2019-1969-1
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container label and carton labeling and Prescribing Information received on May 27, 2020 for calcipotriene/betamethasone dipropionate. Division of Dermatology and Dentistry (DDD) requested that we review the revised container label and carton labeling and Prescribing Information for calcipotriene/betamethasone dipropionate (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The Applicant implemented all of our recommendations from our previous review. However, the Applicant also received a recommendation regarding adding the following statement to the container label and carton labeling: "*Date of first opening __/__/__. Discard unused portion 6 months after first opening.*". We note this statement has been added to the carton labeling. We find the carton labeling and Prescribing Information acceptable from a medication error perspective. Per Applicant, the statement "Date of first opening __/__/__" has been omitted on the container label due to space limitations on the tube and because writing directly on the

[a] Patel, M. Label and Labeling Review for calcipotriene/betamethasone dipropionate (NDA 213422). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 31. RCM No.: 2019-1969.

primary container is not recommended. While we find the rational acceptable, we continue to recommend adding the statement “Discard unused portion 6 months after opening.” To the container label.

3 RECOMMENDATIONS FOR MC2 THERAPEUTICS LTD

We recommend the following be implemented prior to approval of this NDA:

A. Add the “Discard unused portion 6 months after first opening.” statement on the container label to minimize the risk for deteriorated drug medication errors.

APPENDIX A. IMAGES OF LABEL AND LABELING RECEIVED ON MAY 27, 2020

Prescribing Information

Available at

\\cdsesub1\evsprod\nda213422\0022\m1\us\draft-labeling-text.pdf

Container label

(b) (4)

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MADHURI R PATEL
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Clinical Inspection Summary

Date	05/19/2020
From	Jenn Sellers, M.D., Ph.D., Medical Officer Good Clinical Practice Assessment Branch Division of Clinical Compliance Evaluation Office of Scientific Investigations (OSI)
To	David Nartey, Pharm.D., Regulatory Project Manager Kevin Clark, M.D., Clinical Reviewer Gordana Diglisic, M.D., Clinical Team Leader Division of Dermatology and Dentistry (DDD)
NDA #	213422
Applicant	MC2 Therapeutics Ltd
Drug	Calcipotriene/Betamethasone
NME	No
Therapeutic Classification	Vitamin D Analog and Corticosteroid
Proposed Indication	Treatment of Plaque Psoriasis
Consultation Request Date	12/18/2019
Summary Goal Date	05/20/2020
Action Goal Date	07/02/2020
PDUFA Date	07/20/2020

I. OVERALL ASSESSMENT OF FINDINGS AND RECOMMENDATIONS

The clinical site of Dr. Godwin was inspected in support of this NDA. Based on the result of this inspection, the study (Protocol MC2-01-C2) appears to have been conducted adequately, and the data generated by this site appear acceptable in support of the respective indication.

The clinical site of Dr. Boyce (Site 30, Michigan) was initially also selected for inspection. However, at the current time, the COVID-19 global pandemic has significantly limited our ability to conduct on-site GCP inspections. As a result, and in an effort to protect the health, safety, and welfare of FDA employees and study staff, the need for this planned inspection in support of NDA 213422 was reevaluated. Following discussion between OSI and DDD, a decision was made that assessment of the application could proceed without inspection of Dr . Boyce.

II. BACKGROUND

MC2 Therapeutics Ltd submitted this NDA 213422 to support the use of Wynzora cream (calcipotriene/betamethasone dipropionate cream, 0.005%/0.064%) for the treatment of plaque psoriasis.

A clinical inspection was conducted for Protocol MC2-01-C2. The following is the brief description of the protocol.

Protocol MC2-01-C2

Title: "A Randomized, Multicenter, Investigator-Blind, Parallel-Group Trial to Evaluate the Efficacy and Safety of MC2-01 Cream Compared to MC2-01 Cream Vehicle and Active Comparator in Subjects with Mild-to-Moderate Psoriasis Vulgaris"

The primary study objective was to show therapeutic non-inferiority of MC2-01 cream to active comparator Taclonex topical suspension as well as to characterize the safety profile of MC2-01 cream in subjects with psoriasis vulgaris.

The primary efficacy endpoint was the proportion of subjects in each treatment group with 'treatment success' at Week 8 (Visit 6), defined as a minimum 2-point decrease from Baseline to Week 8 on the Physician's Global Assessment (PGA) of disease severity on the trunk and limbs, i.e., a score of 0 (clear) or 1 (almost clear) disease for subjects with moderate disease at Baseline or a score of 0 (clear) for subjects with mild disease at Baseline.

Rationale for Site Selection

The clinical investigator (CI) site was selected for inspection due to large enrollments treatment effect size, protocol deviations, and prior inspection history.

III. RESULTS

Loyd Godwin, M.D.
Site #44
4 Corporate Dr. Suite 386
Shelton, CT 06484
Inspection dates: 02/18/2020 - 02/20/2020

At this site for Protocol MC2-01-C2, a total of 19 subjects were screened, 17 were enrolled and randomized, one discontinued due to loss to follow up, and 16 subjects completed the study.

The informed consent forms for all 19 screened subjects and the study records for all 17 enrolled subjects were reviewed. These records included, but were not limited to, 1572 form, financial disclosure; site training records; correspondence between the CI and the sponsor; correspondence between the CI and the Institutional Review Board (IRB); IRB approval letters; the sponsor monitoring log; drug accountability log and temperature logs of study drugs; medical history and previous treatment; physical exams; efficacy endpoint data; adverse events/serious adverse events; electronic data capture (EDC) audit trails; protocol deviations; and subjects drug dispensation records. No issues were found.

The primary efficacy endpoint data were verified against the data line listings provided by the sponsor; no discrepancies were noted. There was no evidence of underreporting of adverse events.

{See appended electronic signature page}

Jenn W. Sellers, M.D.
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

CONCURRENCE:

{See appended electronic signature page}

Phillip Kronstein, M.D.
Team Leader
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
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CONCURRENCE:

{See appended electronic signature page}

Kassa Ayalew, M.D., M.P.H
Branch Chief
Good Clinical Practice Assessment Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

cc:
Central Doc. Rm. NDA 213422
DDD /Project Manager/David Nartey
DDD/Medical Officer/Kevin Clark
DDD/Clinical Team Leader/Gordana Diglisic
OSI/Office Director/David Burrow
OSI/Deputy Office Director/Laurie Muldowney
OSI/DCCE/Division Director/Ni Khin
OSI/DCCE/Branch Chief/Kassa Ayalew
OSI/DCCE/Team Leader/Phillip Kronstein
OSI/DCCE/GCP Reviewer/Jenn Sellers
OSI/GCP Program Analyst/Yolanda Patague

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/s/

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	May 11, 2020
To:	David Nartey, PharmD Regulatory Project Manager **Division of Dermatology and Dentistry (DDD)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Shawna Hutchins, MPH, BSN, RN Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Laurie Buonaccorsi, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	WYNZORA (calcipotriene and betamethasone dipropionate)
Dosage Form and Route:	Cream, for topical use
Application Type/Number:	NDA 213422
Applicant:	MC2 Therapeutics Ltd (Part of MC2 Therapeutics)

1 INTRODUCTION

On September 20, 2019, MC2 Therapeutics Ltd (Part of MC2 Therapeutics), submitted for the Agency's review an original New Drug Application (NDA-213422) for WYNZORA (calcipotriene and betamethasone dipropionate) Cream, for topical use, for the proposed indication of treatment of patients with plaque psoriasis.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Dermatology and Dentistry (DDD) on November 20, 2019 and November 19, 2019, respectively, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for WYNZORA (calcipotriene and betamethasone dipropionate) Cream, for topical use.

2 MATERIAL REVIEWED

- Draft WYNZORA (calcipotriene and betamethasone dipropionate) PPI received on September 20, 2019 and received by DMPP and OPDP on May 7, 2020.
- Draft WYNZORA (calcipotriene and betamethasone dipropionate) Prescribing Information (PI) received on September 20, 2019, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on May 7, 2020.
- Approved TACLONEX (calcipotriene and betamethasone dipropionate) Topical Suspension labeling dated July 25, 2019.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the PPI the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the PPI document using the Arial font, size 10.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language

- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the PPI is consistent with the approved comparator labeling where applicable.

4 CONCLUSIONS

The PPI is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the PPI is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI.

Please let us know if you have any questions.

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LASHAWN M GRIFFITHS
05/11/2020 02:32:34 PM

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: May 11, 2020

To: Kevin Clark, MD/Clinical Reviewer, M.D.
Division of Dermatology and Dentistry (DDD)

David Nartey, Regulatory Project Manager, (DDD)

From: Laurie Buonaccorsi, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Matthew Falter, Team Leader, OPDP

Subject: OPDP Labeling Comments for calcipotriene and betamethasone dipropionate cream, for topical use

NDA: 213422

In response to DDD's consult request dated November 19, 2019, OPDP has reviewed the proposed product labeling (PI), patient package insert (PPI), and carton and container labeling for the original NDA submission for calcipotriene and betamethasone dipropionate cream, for topical use.

PI and PPI: OPDP's comments on the proposed labeling are based on the draft PI received by electronic mail from DDD on May 7, 2020.

A combined OPDP and Division of Medical Policy Programs (DMPP) review will be completed, and comments on the proposed PPI will be sent under separate cover.

Carton and Container Labeling: OPDP has reviewed the attached proposed carton and container labeling submitted by the Sponsor to the electronic document room on September 20, 2019, and our comments are provided below.

Thank you for your consult. If you have any questions, please contact Laurie Buonaccorsi at (240) 402-6297 or laurie.buonaccorsi@fda.hhs.gov.

Calcipotriene/betamethasone container/carton labeling comments NDA 213422

1. We recommend that the established name be revised to have prominence commensurate with the proprietary name. The established name should be at least half as large as the letters comprising the proprietary name and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features, according to 21 CFR 201.10 (g)(2). The proprietary name is more than twice the size of the established name. We recommend revision.
2. The "(b) (4)" graphics and references on the labels may be promotional. We recommend deletion.

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/s/

LAURIE J BUONACCORSI
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LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	January 31, 2020
Requesting Office or Division:	Division of Dermatology and Dental Products (DDDP)
Application Type and Number:	NDA 213422
Product Name, Dosage Form, and Strength:	(calcipotriene/betamethasone dipropionate) cream, 0.005%/0.064%
Product Type:	Multi-Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MC2 Therapeutics Ltd
FDA Received Date:	September 20, 2019, November 14, 2019, and December 5, 2019
OSE RCM #:	2019-1969
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 REASON FOR REVIEW

MC2 Therapeutics Ltd submitted a 505(b)2 NDA for (calcipotriene/betamethasone dipropionate) cream (NDA 213422). We reviewed the proposed Prescribing Information (PI), Patient Package Insert (PPI), container label, and carton labeling for areas of vulnerability from a medication error perspective.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Label and Labeling Review

Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B– N/A
Human Factors Study	C – N/A
ISMP Newsletters*	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F – N/A
Labels and Labeling	G

N/A=not applicable for this review
*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 OVERALL ASSESSMENT OF THE MATERIALS REVIEWED

We performed a risk assessment of the proposed PI, patient package insert, container label, and carton labeling for (calcipotriene/betamethasone dipropionate) cream for areas of vulnerability that may lead to medication errors. Our review of the proposed labeling identified several areas that can be improved to increase the prominence of important information (e.g. established name and strength). We note the use of the proposed proprietary name, Wynzora*** which we found unacceptable due to potential confusion with another name that was also under review[a]. We also note the container label and carton labeling can be improved to facilitate product identification and to minimize deteriorated drug errors. We were unable to locate a linear barcode on the container label and the lot and expiration date on both the container label and carton labeling. Additionally, the carton labeling would need both a linear

[a] Patel, M. Proprietary Name Review for Wynzora*** (NDA 213422). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 DEC 16. Panorama No. 2019-34589622.

barcode as well as a 2D barcode presented in accordance to the Drug Supply Chain Security Act (DSCSA).

4 CONCLUSION & RECOMMENDATIONS

The container label and carton labeling can be improved to increase the prominence of important information, to minimize potential deteriorated drug errors, and to facilitate product identification.

4.1 RECOMMENDATIONS FOR DIVISION OF DERMATOLOGY AND DENTAL PRODUCTS (DDDP)

A. Prescribing Information and Patient Package Insert

1. The proposed proprietary name, Wynzora***, used throughout the prescribing information (PI) and Patient Packaging Insert (PPI), was found unacceptable by DMEPA under NDA 213422 on December 16, 2019 due to potential confusion with another name that was also under review. Remove the proposed proprietary name, Wynzora***, throughout the PI and PPI. Until a new name is found to be conditionally acceptable, the placeholder, "TRADENAME" may be used.
2. We note in the PI and PPI the established name is written as "calcipotriene and betamethasone dipropionate" and strength is written as "0.005%/0.064%". We defer to the division on whether the two ingredients should be separated by "and" or "/". Ensure that the established name and strength presentation is consistent throughout the labels and labeling.
3. How Supplied/Storage and Handling Section
    a. As currently presented the National Drug Code (NDC) is denoted by a placeholder (NDC XXX). Replace this NDC placeholder with the actual NDC when it is determined.

4.2 RECOMMENDATIONS FOR MC2 THERAPEUTICS LTD

We recommend the following be implemented prior to approval of this NDA:

A. General Comments (Container label & Carton Labeling)

1. The proposed proprietary name, Wynzora, used throughout the container label and carton labeling, was found unacceptable by DMEPA under NDA 213422 on December 16, 2019 due to potential confusion with another name that was also under review. Remove the proposed proprietary name, Wynzora, throughout the PI and PPI. Until a new name is found to be conditionally acceptable, the placeholder, "TRADENAME" may be used. Once a proprietary name is found conditionally acceptable, the placeholder "Tradename" must be replaced with the proprietary name on the container labels and carton labeling and the revised labels and labeling must be submitted to the Agency for review.

2. The established name is not at least half the size of the proprietary name. Revise the established name to be in accordance with 21 CFR 201.10(g)(2).
3. As currently presented the National Drug Code (NDC) is denoted by a placeholder (NDC XXXXXX XXX XX). Replace this NDC placeholder with the actual NDC on both the container label and carton labeling when it is determined.
4. The strength lacks prominence commensurate with the proprietary name. Increase the prominence of the strength taking into account all pertinent factors, including typography, layout, contrast, and other printing features in accordance with 21 CFR 201.15(a)(6).
5. Relocate the net quantity statement away from the product strength, such as to the side or bottom of the principal display panel. From post-marketing experience, the risk of numerical confusion between the strength and net quantity increases when the net quantity statement is located in close proximity to the strength statement.
6. Please note, an "Rx only" statement is required on the drug label by Section 503(b)(4)(A) of the Federal Food, Drug, and Cosmetic Act. Please ensure the "Rx Only" information does not appear more prominent than the established name on the principal display panel.
7. Revise the statement "(b) (4)." to read "See prescribing information for complete information."
8. Expiration date is required on the immediate container and carton labeling per 21 CFR 211.137. To minimize confusion and reduce the risk for deteriorated drug medication errors, identify the format you intend to use. FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format if only numerical characters are used or in YYYY-MMM-DD if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, to be expressed as: YYYY-MM if only numerical characters are used or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or a space be used to separate the portions of the expiration date.
9. Ensure that the lot number statement is present on the container label and carton labeling per 21 CFR 201.10(i)(1).

B. Container Labels

1. The drug barcode is often used as an additional verification before drug administration in the hospital setting; therefore, it is an important safety feature that should be part of the label whenever possible. Therefore, we request you add the product's linear barcode to each individual tube as required per 21CFR 201.25(c)(2). The barcode should be surrounded by sufficient white space to

allow scanners to correctly read the barcode in accordance with 21 CFR 201.25(c)(i).

C. Carton Labeling

1. In September 2018, FDA released draft guidance on product identifiers required under the Drug Supply Chain Security Act.[b] The Act requires manufacturers and repackagers, respectively, to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in(to) commerce beginning November 27, 2017, and November 27, 2018, respectively. The human-readable product identifier contains the NDC, serial number, lot, and expiration date. The DSCSA guidance on product identifiers recommends the format below for the human-readable portion of the product identifier. The guidance also recommends that the human-readable portion be located near the 2D data matrix barcode.

   NDC: [insert product's NDC]
   SERIAL: [insert product's serial number]
   LOT: [insert product's lot number]
   EXP: [insert product's expiration date]

   We recommend that you review the draft guidance to determine if the product identifier requirements apply to your product's labeling.

[b] The draft guidance is available from: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm621044.pdf

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for calcipotriene/betamethasone dipropionate received on December 5, 2019 from MC2 Therapeutics Ltd, and the listed drug (LD).

Table 2. Relevant Product Information for calcipotriene/betamethasone dipropionate and the Listed Drug		
Product Name	calcipotriene/betamethasone dipropionate	Taclonex (Ointment and Topical Suspension, NDA 021852 and 022185)[c]
Initial Approval Date	N/A	Ointment January 9, 2006 Topical Suspension May 9, 2008
Active Ingredient	calcipotriene/betamethasone dipropionate	calcipotriene/betamethasone dipropionate
Indication	topical treatment of plaque psoriasis in patients 18 years of age and older	Ointment topical treatment of plaque psoriasis in patients 12 years of age and older Topical Suspension topical treatment of plaque psoriasis of the scalp and body in patients 12 years and older
Route of Administration	topical	topical
Dosage Form	cream	ointment topical suspension
Strength	0.005%/0.064%	0.005%/0.064%
Dose and Frequency	Apply to affected areas once daily for up to 8 weeks. Patients 18 years and older should not use more than 100 g per week.	Ointment Apply to affected area(s) once daily for up to 4 weeks. Adults patients should not use more than 100 g per week. Patients

[c] Taclonex ointment [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2020 JAN 10. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021852s020lbl.pdf.

Taclonex topical suspension [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2020 JAN 10. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022185s027lbl.pdf.

		ages 12 to 17 years should not use more than 60 g per week. <u>Topical Suspension</u> Apply to affected areas once daily for up to 8 weeks. Patients ages 12 to 17 years should not use more than 60 grams per week. Adult patients should not use more than 100 grams per week.
How Supplied	60 gram tube	<u>Ointment</u> 60 gram and 120 gram tubes <u>Topical Suspension</u> 60 gram bottle and 120 gram (2 bottles of 60 grams)
Storage	Store between 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F).	Store between 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F).
Container Closure	Tube	<u>Ointment</u> Tube <u>Topical Suspension</u> Bottle

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[d] along with postmarket medication error data, we reviewed the following calcipotriene/betamethasone dipropionate labels and labeling submitted by MC2 Therapeutics Ltd.

- Container label received on September 20, 2020
- Carton labeling received on September 20, 2020
- Patient Package Insert (Image not show) received on November 14, 2019, available from \\cdsesub1\evsprod\nda213422\0005\m1\us\patient-information.pdf
- Prescribing Information (Image not shown) received on December 5, 2019, available from \\cdsesub1\evsprod\nda213422\0007\m1\us\draft-labeling-text.pdf

G.2 Label and Labeling Images

Container Label

(b) (4)

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[d] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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