Participant Information Sheet

MEDICAL RESEARCH INSTITUTE OF NEW ZEALAND

Study title:	**3% Kānuka Oil Cream for the Treatment of Eczema**
Ethics committee ref.:	**18/CEN/152**
Lead investigator:	**Dr Alex Semprini**
Contact phone number:	**(04) 805 0260**

You are invited to take part in a study on eczema. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form at the end of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of the study?

Eczema is a term for a group of inflammatory skin conditions with similar features. These conditions normally present as a chronic, relapsing, itchy rash.

Kānuka oil is obtained from the leaves of the Kānuka tree (Kunzea robusta) and it is thought that kānuka oil has multiple properties that may help treat eczema symptoms. This study aims to test a cream containing 3% kānuka oil to see if it is effective for treating eczema. The addition of the kānuka oil may give the cream anti-inflammatory benefits to help with eczema symptoms and anti-bacterial benefits which may reduce the risk of the rash becoming infected. The cream also contains glycerine which will act as a moisturiser.

If you take choose to take part in this study you will randomly (by equal chance) be given either the 3% kānuka oil cream or control cream. The control cream is the same base cream as the kānuka oil cream but does not contain any kānuka oil. The use of a control cream will allow researchers to determine if the cream plus kānuka oil has a greater effect than just the cream by itself. It is currently unknown if the kānuka oil will be effective in the treatment of eczema and because of this there is no known benefit to receiving the kānuka oil cream versus the control cream.

This study is sponsored by Hikurangi Bioactives Limited Partnership, Ruatoria, NZ and is being run in pharmacies around New Zealand by the Medical Research Institute of New Zealand (MRINZ), Wellington, NZ, under the direction of the Lead Study Doctor, Dr Alex Semprini. Contact details for the Dr Semprini and the study team can be found on page 6.

This study has been approved by the Central Health and Disability Ethics Committee (reference: 18/CEN/152).

What will my participation in the study involve?

If you consent to be in the study the pharmacist you are seeing will need to ask you some questions about your health and any medications you are using (the two boxes below) to confirm that you are eligible to participate in the study.

✓	TO TAKE PART IN THIS STUDY YOU MUST:
✓	• Be 18 to 65 years old
✓	• Have a doctor's diagnosis of eczema
✓	• Have an eczema patch, which is typical of your eczema and located below the collarbone, that you are comfortable to have photographed.
✓	• Have a POEM score of 'moderate or severe eczema' (a score of 8 to 24)
✓	• Be willing to stop all moisturisers, skin barrier creams, or emulsion treatments during the study test period and replace them with the treatment assigned in this study
✓	• Be willing to replace your body wash and/or soaps with aqueous cream as supplied at enrolment
✓	• Be able to attend a follow up visit at this pharmacy 6 weeks after you enrol in the study

✗	YOU WILL NOT BE ABLE TO TAKE PART IN THE STUDY IF:
✗	• You have a current need for antibiotics or corticosteroids for the treatment of any condition (with the exception of inhaled and intranasal corticosteroids)
✗	• You have used antibiotics, corticosteroids, calceneurin inhibitors, or antihistamines within the last four weeks (with the exception of inhaled and intranasal corticosteroids)
✗	• You have a fungal or bacterial skin disease needing medical treatment
✗	• You have any other skin condition that may affect the assessment of your eczema
✗	• You have a history of allergy or intolerance to the ingredients of the study treatments: Kānuka oil; Prunus amygdalus dulcis (almond) oil; Glycerine; Cetearyl alcohol; Cetearyl glucoside; Sorbitan olivate; Xanthan gum; Benzyl alcohol; Dehydroacteic acid
✗	• You are pregnant or are planning to become pregnant during the study
✗	• You have participated in a clinical trial in the last three months

If you are eligible, then you will be given a study ID number and randomly (by equal chance) be given either the 3% kānuka oil cream or control cream. We will not tell you which treatment you have received but you will likely be able to tell from the smell of the cream. Both treatments should be applied twice a day, morning and night for six weeks. We also require you to replace your normal body wash and soaps with an aqueous cream that will be supplied to you.

You will also need to answer some questionnaires about your eczema symptoms and how they affect you. You will also have a photograph taken of your skin showing your eczema rash. You can choose the area of your skin that is photographed.

You will be asked to complete an electronic diary via 'sms' or email, recording your eczema symptoms and treatment use every week for five weeks. You will also be provided with a paper diary as a back-up if you cannot access the online version and a prepaid envelope to send this back to the research doctor in Wellington. You will receive a reminder email if you do not complete that week's diary entry within two days of being sent the link.

You will be required to return to the pharmacy for a second visit six weeks later, this visit will be booked at the end of the first visit. Each study appointment will take approximately 30 minutes.

During the second visit you will need to answer some more questionnaires about your eczema symptoms and how they affect you. You will also have another photo taken of the same area of your skin. You will also be asked some questions about how effective the treatment you received was.

Two weeks after your second visit you will receive a survey link in an email. This survey will collect information about any adverse events since stopping the treatment and any comments you have about the study.

The purpose of the photos is to provide a record of your eczema before and after the study test period. The two photos will be assessed by the study dermatologist (skin specialist doctor) who will not know what treatment you received (the kānuka oil cream or the control cream) to see if there is any change in your eczema. The photos will be sent electronically to the dermatologist and will be labelled with your study ID number and initials (your name and identity will remain confidential).

Please be aware we will inform your usual healthcare practitioner that you are participating in this study.

Additionally you may be asked to leave the trial, for the following reasons:

- In the Investigator's opinion it would not be in your best interest to continue in the study
- Any safety concerns
- You do not follow instructions during the study visits

What are the possible benefits and risks of this study?

It is possible that you may experience some stinging or other skin irritation from applying the study creams, and some inconvenience or discomfort in changing from your usual skin care products to the ones supplied for the study. Additionally you may experience a flare up in your eczema symptoms caused by switching treatment.

If you have a known allergy to any ingredient in the kānuka oil or control creams you will not be able to take part in this study. If you have a suspected allergic reaction on your skin when you attend the follow up visit, a photograph will be taken for the study dermatologist to assess. This assessment will not replace your normal healthcare provider and you should seek their medical advice.

Additionally, while there are no perceived risks, it should be noted that there is no current safety information around the use of this treatment during pregnancy.

Who pays for the study?

It does not cost anything to participate in this study. The study cream and body wash/soaps are provided to you free of charge. You will be reimbursed a total of $200 via cheque or direct bank credit for your study expenses, on completion of the two study visits and five weekly diaries.

The pharmacies receive reimbursement for the time involved in participating in the study and for the loss of sold product.

What if something goes wrong?

As this research study is for the principal benefit of its commercial sponsor Hikurangi Bioactives Limited Partnership, if you are injured as a result of taking part in this study you **won't** be eligible for compensation from ACC.

However, Hikurangi Bioactives Limited Partnership has satisfied the Central Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical guidelines for intervention studies require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand's ACC scheme.

Some sponsors voluntarily commit to providing compensation in accordance with guidelines that they have agreed between themselves, called the Medicines New Zealand Guidelines (Industry Guidelines).These are often referred to for information on compensation for commercial clinical trials. There are some important points to know about the Industry Guidelines:

- On their own they are not legally enforceable, and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
- The Sponsor may not accept the compensation claim if:

- your injury was caused by the investigators, or;
- There was a deviation from the proposed research plan, or;
- Your injury was caused solely by you.

An initial decision whether to compensate you would be made the by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to take action through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

You are strongly advised to read the Industry Guidelines and ask questions if you are unsure about what they mean for you.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

During the study your health care remains with your regular medical practitioner. In the unlikely event a reaction to the study cream occurs that concerns you or you require medical advice, please see your regular medical practitioner for their medical advice. Please also contact the study doctor (Dr Alex Semprini) using the contact details given at the end of this information sheet, it is possible that he may advise you to withdraw from the study.

Please note that during the study if you see your regular medical practitioner for anything related to your eczema it will be at your own expense. You may be able to claim for compensation if there has been a reaction to the study cream from the Sponsor but compensation will be given on a case by case basis.

If an adverse event occurs during the study the study investigators may need to contact your usual healthcare practitioner to gather information about this event including diagnosis, dates of event, and treatments prescribed. If you become pregnant during the study we will need to contact you once the baby is born to follow up on the health of the baby.

What are my rights?

Participation in this study is completely voluntary (your choice). You are free to decline to participate or withdraw from the study at any time.

The study Investigators will contact you if new information is discovered during the study which may affect your health or participation in the study.

Your personal information including the photos taken of your skin will be securely held by pharmacy staff, the study dermatologist and research staff at the MRINZ for study analysis and follow-up. The study dermatologist will not have full identifying details of you (such as your name or address) but will only have records stating your study ID number and initials.

The electronic data we hold for the study will be stored on protected, secure servers that may be located overseas. All electronic and paper hardcopy study data and records will be held for at least 15 years then destroyed. You will not be identifiable in any published study results. You may request a copy of your individual study records if you wish. A regulatory authority or auditor appointed by the ethics committee that approved this study may access your medical records in relation to the study solely for the purpose of checking the study has been run properly.

What happens after the study or if I change my mind?

Once the study has finished and the data has been analysed the results will be made available to you on your request. You will have the opportunity to request a copy of the study results when you sign the informed consent form.

You may withdraw from the study at any time. If you would like to withdraw, please inform a member of the study team. If you wish you may ask the study team to withdraw your data from the study results. In the absence of any specific instructions from you, we will use the data you have provided up until the point of your withdrawal.

Please be aware you will not have access to the study treatments once you finish the study.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

MRINZ Lead Study Doctor

Name:	Dr Alex Semprini
Telephone number:	04 805 0260
Email:	kanuka.oil@mrinz.ac.nz

MRINZ Study Coordinator

Name:	Nick Shortt
Telephone number:	04 805 0236
Email:	kanuka.oil@mrinz.ac.nz

Independent Health and Disability Advocate

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

Maori Health Support

Name:	Matire Harwood
Telephone number:	+64 9 923 7866

Health and Disability Ethics Committee (HDEC)

Phone:	0800 4 ETHICS (0800 438 4427)
Email:	hdecs@moh.govt.nz