



**SUBJECT INFORMATION (version 2: 0194 - 15 Aug 2007)**

This information sheet should be retained by you along with a signed copy of the consent form

- You are being invited to take part in a research study.
- It is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully and discuss it with others if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part.

**Study Title:**

**A Double-blind, Placebo controlled, Pilot Clinical Evaluation of the efficacy of topical salicylic acid in combination with dietary supplements compared in improving the appearance of facial skin**

**What is the purpose of the study?**

We are conducting a study to investigate the effects of dietary supplements on skin blemishes and spots. Evidence suggests that the incidence of acne is considerably lower in non-Westernised societies and Western diets are typically lower in certain fish oils. Therefore, increasing the levels in the diet could help reduce the rate and/or severity of skin blemishes and spots. By combining dietary supplements with a topical gel which reduces inflammation and normalises skin turnover, we hope to provide an alternative way of treating spots and blemishes without resorting to more aggressive therapies.

**Why have I been asked to take part?**

You have been invited to take part in this study because you have mild acne on the face. We are inviting people with approximately 15 - 20 red spots on the face to take part in this research project.

**Do I have to take part?**

It is up to you to decide whether or not to take part.  
If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form.  
**Taking part in this study is entirely voluntary.**  
If you decide to take part you are still free to withdraw at any time and without giving a reason.  
You can also be withdrawn from the study by the Investigators at any time if this is regarded as being in your interest.

**What will happen to me if I take part?**

You will be one of 120 individuals taking part. You will be required to take dietary supplements in capsule form and apply a topical gel every day for 12 weeks. You will be required to visit us at the start of the study and after 6 and 12 weeks, to have your skin assessed.

**What do I have to do? You have take two types of capsule (six in total) everyday and apply the gel to face twice a day. We will ask you to fill-in a record card every time you use the treatments. You will also have to provide a urine sample at each visit so that we can see how your body is handling the nutrients in the capsules.**

**What is being tested?**

You will be given either an active or placebo gel to apply to your face. The active gel contains salicylic acid and is a typical cosmetic product. Everyone will also receive two types of capsule to be taken orally with meals. The capsules will contain enriched fish oil, sunflower oil and/or plant-derived ingredients in a variety of combinations, depending upon which group you are in.

**What are the side effects of taking part?**

All products are freely available as either cosmetic or nutritional supplement products. Under normal use there are no known side-effects.

<b>Title:</b> Pilot Clinical Evaluation of the efficacy of topical salicylic acid and dietary supplements in improving the appearance of facial skin					
<b>Study No:</b> SRC-0194	<b>Patient Information Sheet</b>	<b>Author:</b> R. Bojar	<b>Version:</b> 2	<b>Date:</b> 15 Aug 2007	<b>page:</b> 1 of 2



# SKIN RESEARCH CENTRE

## What are the possible disadvantages and risks of taking part?

None that we are aware of.

## What are the possible benefits of taking part?

Depending upon the product combination you are given, you may experience improvements to the appearance of your skin and reduced inflammation.

## What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the product that is being studied. If this happens, you will be told about it and you will be asked whether you want to continue in the study. You may decide to withdraw or, if you decide to continue in the study, you will be asked to sign an updated consent form.

## What if something goes wrong?

In the unlikely event that there is any significant deterioration in health or well-being arising as a result of taking part in this study, Unilever has undertaken to compensate without having to prove that anyone involved in this study has been negligent. Additionally, compensation for injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). You will be covered by the University's public liability policy which will indemnify University staff for their legal liability for accident or injury to third parties. This means that if anyone is injured as a result of the negligence of anyone acting for the University, the third party is entitled to make a claim against the University for their injury. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. Compensation will not be forthcoming where such injury results from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected.

## Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Data collected in this study will be used in an anonymous format at all times and kept in accordance with the data protection act. In order to check that the study is being carried out correctly, information about you and the data we collect may be inspected by the sponsor during routine monitoring visits, the regulatory authorities and independent auditors.

**N.B. PHOTOGRAPHS** - Part of the assessment will include a full face photograph which will be treated as confidential clinical data. However, it is possible that the sponsor may want to use your photographs in future publicity material. If you are happy for this to happen, please indicate your preference on the consent form. Otherwise, by default, your photographs will be treated as confidential data and will not be available to the sponsor for publicity purposes. Images will be held in secure storage at the Skin Research Centre for 5 years after which they will be destroyed in accordance with the Data Protection Act (1998).

## What will happen to the results of the research study?

The results of the study may be submitted for publication in the scientific literature and used by the sponsor to develop it's product line.

## Who is funding the research?

This study is being financed by Unilever R&D.

You will be paid £60 for completing the study (£20 at visit 1, £20 at visit 2, £20 at visit 3).Contacts:

### For further information:

Dr. Richard Bojar, Skin Research Centre, Research Institute of Molecular and Cellular Biology, Faculty of Biological Sciences, University of Leeds

tel: (0113) 3435615 fax: (0113) 343 5638 email: [r.a.bojar@leeds.ac.uk](mailto:r.a.bojar@leeds.ac.uk)

### Complaints regarding the conduct of the study:

Dr. David Marples, School of Biomedical Sciences, University of Leeds

tel: (0113) 3434245 fax: (0113) 3434228 email: [d.d.r.marples@leeds.ac.uk](mailto:d.d.r.marples@leeds.ac.uk)

<b>Title:</b> Pilot Clinical Evaluation of the efficacy of topical salicylic acid and dietary supplements in improving the appearance of facial skin					
<b>Study No:</b> SRC-0194	<b>Patient Information Sheet</b>	<b>Author:</b> R. Bojar	<b>Version:</b> 2	<b>Date:</b> 15 Aug 2007	<b>page:</b> 2 of 2



# UNIVERSITY OF LEEDS