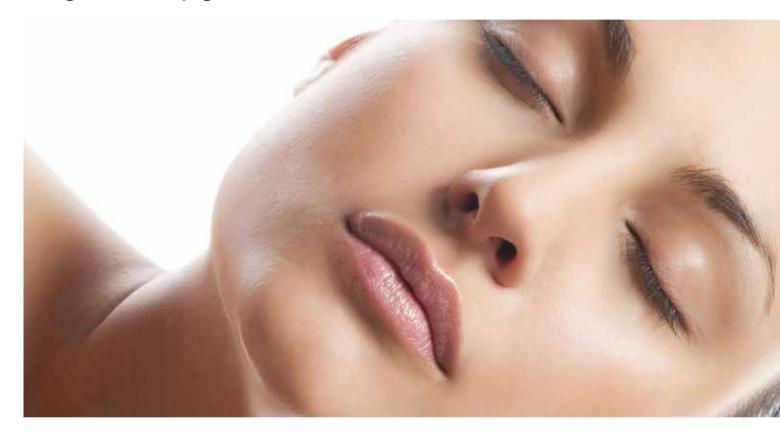


# NAB® Butterbur Extract Phytotherapy for Sensitive Skin



INCI: Water and *Petasites japonicus* Root Extract SAP #: 138620

# **Key Product Attributes**

- Naturally based active
- Reduces histamine expression in vitro
- In vitro anti-irritant efficacy
- Soothing effect
- Reduces appearance of redness or blotchiness
- For all skin types: especially sensitive skin
- Counters irritating activities such as chemical peels, whitening, shaving, cleansing, waxing, etc.

# Introduction

The prevalence of people who have self-assessed "sensitive" skin is significant and epidemiological studies suggest that the problem crosses ethnic and gender lines. 1-3 Unfortunately, it is often difficult to accurately define exactly what it means when one suggests that they have sensitive skin. Likewise, the processes by which the skin responds to external threats are complex and multifaceted. Depending on the nature of the threat, the response can be subtle, such as light redness or itching, to significant with major skin eruptions, blistering and even possibly infection.<sup>4–5</sup> These varying responses are principally the result of the host of cells and chemicals the body brings to bear on a potential threat. For instance, the body may respond to a mild surfactant treatment with development of faint redness (erythema) and possibly some itching. On the other hand, exposure to the allergen urushoil which is found in many plants such as poison ivy and poison sumac can cause a significant immune response (contact hypersensitivity) with formation of blisters, severe itching and swelling.6

Efforts by consumers to try and stave off the signs of aging including the development of wrinkles, skin hyperpigmentation and sagging are pushing people to use more and more aggressive skin treatment regiments. "At home" dermal abrasion kits, peels, and even more aggressive skin stripping regiments such as lasers can leave the skin red, inflamed and sensitive. Yet, treatments such as these can be routinely purchased in the consumer aisles of any grocery store. Seeking naturally-based extracts that can ameliorate some of these cutaneous responses is desirable.



Petasites japonicus

#### Mast cell and dermal neural cell intercommunication schematic.

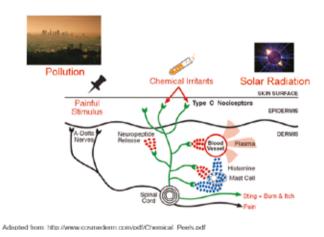


Fig. 1

# **Product Background**

To address the different concerns of sensitive skin, Lonza Consumer Care has developed a new raw material from Butterbur (Petasites japonicus), NAB® Butterbur Extract. The Butterbur herb can be found growing in wet, low-lying, marshy meadows and it grows commonly by river banks.7-8 The species Petasites japonicus is common in the colder, northern regions of Russia and Europe. The leaves of the fully grown herb can attain diameters of up to three feet. The origin of the name Butterbur stems from the Colonial days, where the large leaves from the plant were used to wrap butter during hot weather, in order to keep it cool. Extracts from the leaves and roots were used in ancient Greek times, as an anti-inflammatory, a smooth muscle relaxant (anti-spasmodic) and pain reliever (analgesic).8 It is suggested that extracts of Butterbur "... do wonderfully help to dry up the moisture of the sores that are hard to be cured and takes away all spots and blemishes of the skin". 9 The antiallergenic properties of the aerial portion of the plant can be attributed to the eremophilane type sesquiterpenes (of which Petasin & Iso-Petasin are major constituents), fukinone and hydroxyfukinone.8 Butterbur has been found to be effective at helping to relieve discomfort in sensitive skin associated with irritation and rosacea.7

Examination of an aqueous extract of NAB® Butterbur Extract via HPLC shows it to be a complex mixture of many components, Figure 2.

#### HPLC Chromatogram of NAB® Butterbur.

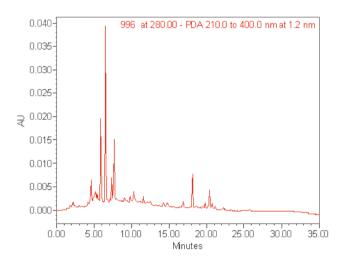


Fig. 2

# In Vitro Efficacy Studies

### Histamine Release Study on Mast Cells

#### Controlling the Itch

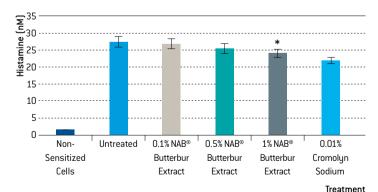
In the allergy process, potential allergens are first recognized by special immune cells such as T-cells. In response to the allergen, the T-cells will produce IgE antibodies which recognize the specific allergen. These IgE antibodies are then released by the T-cells and will bind to specific receptors on the surface of mast cells. Mast cells are histamine- and leukotriene-containing immune cells, and when they are bound to IgE antibodies they become sensitized to that specific allergen. When exposed to the allergen for a second time, the allergen will bind to the IgE antibodies already bound to the mast cell, which triggers a sequence of events that results in the release of histamine and leukotriene from secretory granules located within the mast cell. This process is called "degranulation". It is the local effect of this released histamine and leukotriene that is responsible for the systemic symptoms associated with allergic responses.

In the assay system used in this study, a mast cell model was incubated with an anti-dinitrophenyl (DNP) IgE antibody to sensitize the cells to DNP. After this incubation, the cells were washed to remove any unbound IgE and then incubated with DNP in the presence or absence of test materials; NAB® Butterbur Extract (at different concentrations) and Cromolyn Sodium (as a positive reference). After this second incubation, histamine release was assayed using ELISA based measurements to determine histamine release.

# Histamine Release Assay

#### In Vitro Histamine Release Study on Mast Cells

NAB® Butterbur Extract was compared against a positive control, Cromolyn Sodium, for its ability to reduce histamine expression in previously sensitized mast cells. Cromolyn Sodium is a commonly used active in OTC allergy medications, and was used as a positive control.



Graph 1

## Leukotriene Release Study on Mast Cells

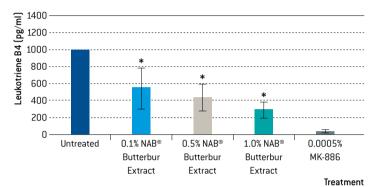
#### **Controlling Inflammation and Redness**

Using the same cell culture system as described above, NAB® Butterbur Extract was examined for its influence on the ability to reduce leukotriene release. Results from this study are shown in Graph 2.

## Leukotriene Release Assay

#### In Vitro Leukotriene Release Study on Mast Cells

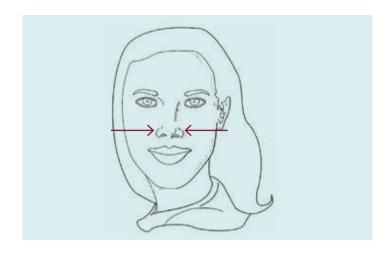
NAB® Butterbur Extract was compared against MK-886, a known leukotriene inhibitor, to determine its ability to reduce leukotriene release in previously sensitized mast cells.



Graph 2

# In Vivo Lactic Acid Stinging Study

An *in vivo* lactic acid stinging study was conducted to evaluate the ability of NAB® Butterbur Extract to provide a soothing effect on skin, from the stinging sensation typically felt by people who are sensitive to lactic acid. The study was a seven day, half-face, double blind protocol. Potential panelists were prescreened for their ability to 'sting' to lactic acid. Stingers were chosen for inclusion in the final panel, as determined by their reaction to the lactic acid screening treatment on their skin. 30 panelists were selected for the actual study, whereby they applied twice daily for seven days the test product to one side of their nasogenial furrow, and a control placebo product to the other side. During the testing period, a 10% lactic acid solution was applied to each side of the face, and a subjective stinging rating was conducted by each panelist following lactic acid treatment at the following time points: 10 seconds, 2.5 minutes and 5 minutes.



#### Results

Following the 10-second assessment time, when compared to the placebo control, the test product containing NAB® Butterbur Extract immediately reduced the stinging sensation felt post-lactic acid treatment by 20%. In fact, the NAB® Butterbur Extract completely ameliorated the stinging effect felt by this treatment. At both 2.5 and 5 minutes, there was no difference between NAB® Butterbur Extract and control treatment.

## Conclusions

NAB® Butterbur Extract, demonstrates an ability to minimize mast cell degranulation *in vitro*. Control of mast cell degranulation and release of both histamine and leukotriene can be important indications of a product's ability to help minimize irritation and inflammation cascades in the skin. NAB® Butterbur Extract reduces the sting response triggered from a lactic acid sting as shown *in vivo*. This type of performance suggests that NAB® Butterbur Extract may help aid in numerous areas and products where inflammation and irritation responses and even sensitive skin are anticipated or expected to occur or be a problem.

NAB® Butterbur Extract Typical Properties	
Appearance	Clear to slightly hazy amber liquid
Color (Gardner)	5–15
рН	4.5–6.5
NVM (1g, 1hr, 105°C)	0.5–3.5%
Microbial Content	100 opg Maximum; No Pathogens
Preservative System	0.25–0.75% Potassium Sorbate 0.9–1.1% Phenoxyethanol
Recommended Use Level	1–5%

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