




# Eczema / Atopic Dermatitis

Patient information booklet

 **Protopic<sup>®</sup>**  
tacrolimus 0,03%,  
0,1% ointment

This leaflet is only for patients that have been prescribed Protopic.

# WHAT IS ECZEMA/ATOPIC DERMATITIS?

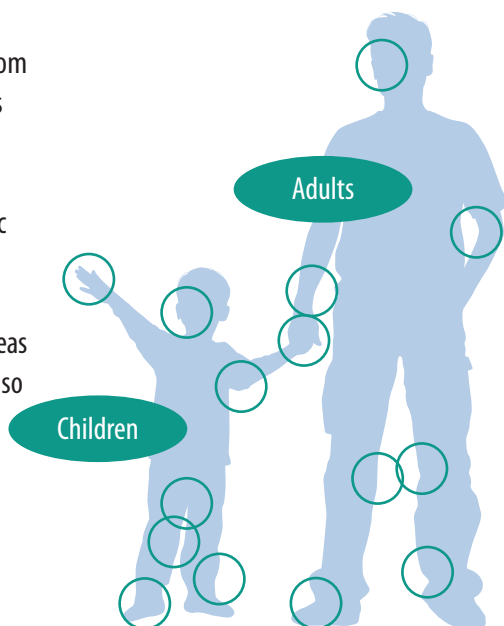
**Atopic dermatitis is often referred to as eczema.<sup>1</sup> Dermatitis is inflammation of the skin that can flare up from time to time. The word “atopic” describes allergic tendencies. People with atopic dermatitis often have other conditions where allergy is involved, e.g. asthma or hay fever<sup>2</sup>**

Atopic dermatitis or eczema is one of the most common skin conditions, affecting up to 20 % of children and 2 – 5 % of young adults. It is a chronic (long-lasting) condition, but symptoms can be controlled with treatment<sup>3</sup>

# WHAT ARE THE SYMPTOMS OF ATOPIC ECZEMA?

Symptoms vary from person to person but **extreme itching is a very common** symptom of atopic dermatitis.<sup>1,4</sup> The skin usually feels dry, and can become red and inflamed

The **most common areas** affected by atopic eczema are **next to skin creases**, such as the **front of elbows** and **wrists** or **behind knees**, and **around the neck**. Other skin areas may also be involved.<sup>1,2</sup> Atopic eczema may also affect the skin around the eyes, the eyelids, and the eyebrows and lash line<sup>1</sup>

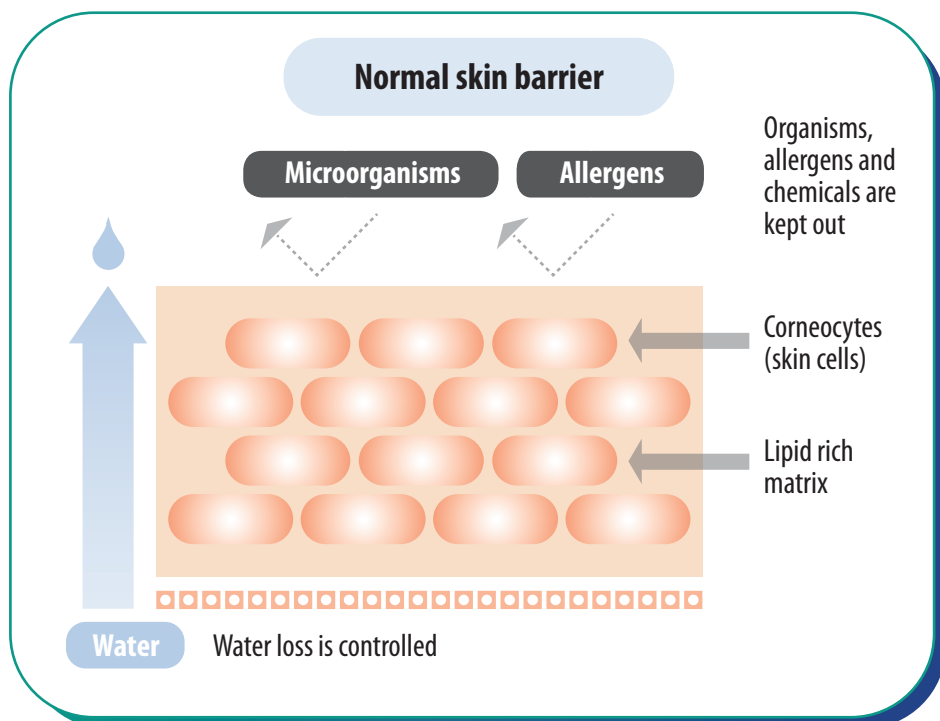


Scratching and rubbing in response to itching irritates the skin, increases inflammation, and actually increases itchiness. Itching is a particular problem during sleep when conscious control of scratching is lost<sup>1</sup>

# WHAT CAUSES ATOPIC ECZEMA?

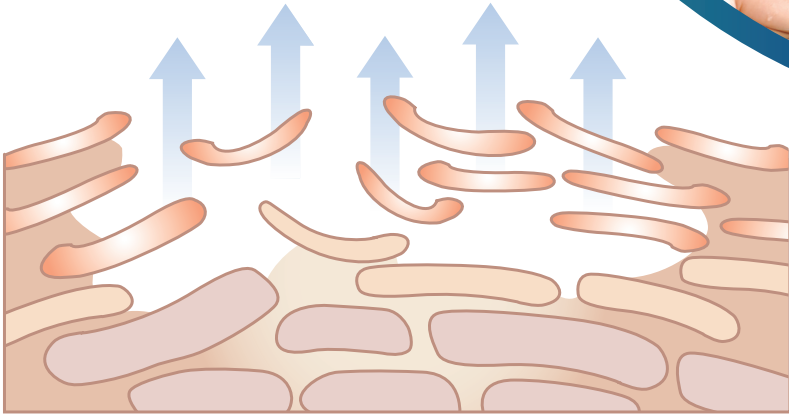
The exact cause of atopic eczema is not known, but the condition seems to stem from a combination of hereditary and environmental factors.<sup>1</sup> Children are more likely to develop atopic eczema if a parent has eczema, or another atopic condition such as asthma or hay fever<sup>1</sup>

The top layer of skin forms a skin barrier, which prevents loss of moisture from the skin and protects the skin from allergens and germs. This barrier is defective in people with atopic eczema, which means that moisture is lost from the skin and the skin becomes dry.<sup>5</sup> Levels of certain essential lipids such as ceramide are lower in the skin of people with atopic eczema. This causes the skin cells to move apart, and moisture is lost from the skin.<sup>6,7</sup>





### Defective skin barrier



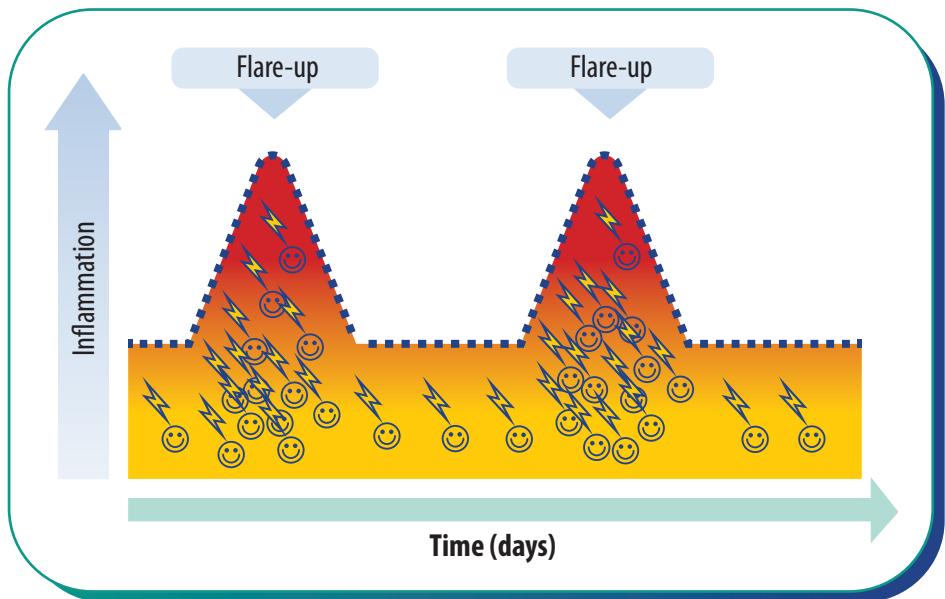
Dry skin, showing increased moisture loss

Atopic eczema has also been associated with a malfunction of the body's immune system (the system that helps recognise and fight bacteria and viruses that enter the body). The immune system can become misguided and create inflammation of the skin<sup>1</sup>

Some factors in the environment associated with allergies can trigger a flare (worsening) of atopic eczema and include allergies to food such as cow's milk or wheat, or allergies to pollen. House dust mites, pet hair and tobacco smoke can all trigger an atopic eczema flare. Woollen clothes or rough textiles may also irritate the skin<sup>3</sup>

# WHAT ARE THE DIFFERENT STAGES OF ATOPIC ECZEMA?

Atopic eczema is a long-lasting, recurring condition.<sup>3</sup> Symptoms usually improve with treatment, but can flare up (worsen) from time to time in between treatments<sup>5</sup>



Adapted from Danby SG, 2010<sup>6</sup>

First symptoms of a flare:<sup>1</sup>



Itchiness



Redness



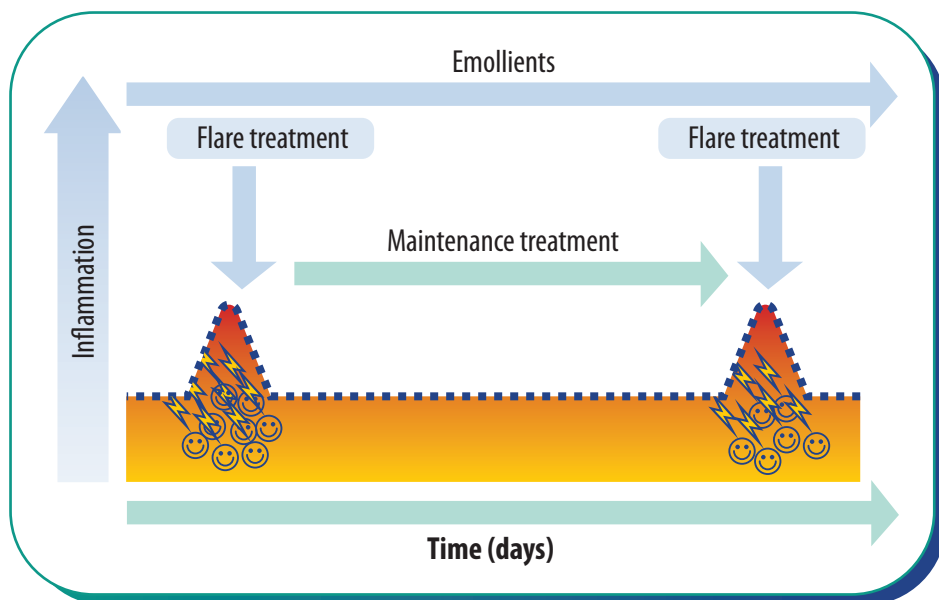
Dry skin



Small raised bumps

# HOW IS ATOPIC ECZEMA TREATED?

Treatment of atopic eczema is aimed at long-term control of symptoms and prevention of flares from occurring<sup>3,5</sup>



Adapted from Danby SG, 2010<sup>1</sup>

## Step 1:

Repair the skin's defective barrier with an emollient<sup>3</sup>

## Step 2:

Control the flare<sup>3,5</sup>

## Step 3:

Maintain control and prevent flares from occurring<sup>3,5</sup>



Remember to use a good emollient throughout, even if there are no flares, as dry skin needs constant maintenance<sup>3,5,8,9</sup>

 **Protopic<sup>®</sup>**  
tacrolimus 0,03%,  
0,1% ointment

## Step 1:

# Repair the skin's defective barrier with an emollient

An emollient is not a regular lotion or cream. It is used on a daily basis to help repair the skin's barrier and to prevent loss of moisture. It moisturises the skin, improves dryness and subsequently itchiness<sup>3,8</sup>

**SBR® Repair is a medically formulated emollient for accelerated repair and maintenance of the skin barrier<sup>8,10</sup>**

**SBR® Repair** contains the three most important skin lipids (ceramide, cholesterol and fatty acids) in the right ratio to facilitate repair of the skin's defective barrier.<sup>8</sup> Its patented nanoparticles help **SBR®** to penetrate deeper into the skin layers and to work more effectively to restore the skin's barrier.<sup>8</sup> The nanoparticles also form a layer on the skin to prevent further loss of moisture from the skin's surface and to keep other irritants out. This layer has a matt finish which makes it cosmetically acceptable<sup>8</sup>

When the skin's barrier is impaired, the pH of the skin rises. **SBR® Repair** has the correct pH to help re-acidify atopic skin to assist with healing<sup>8</sup>

**SBR® Repair** has been shown to effectively improve eczema symptoms, improve itchiness, repair the skin's defective barrier and decrease loss of moisture from the skin's surface.<sup>8,11,12</sup>

**SBR® Repair** may be used with topical corticosteroids or **PROTOPIC®**.<sup>3</sup> It contains no perfume, colourants or Sodium Lauryl Sulphate (SLS) that could irritate an atopic skin<sup>8</sup>





The SBR® Range consist of two formulations, SBR® Repair and SBR® Lipocream. These are specially formulated to treat dry skin conditions at various stages:<sup>13</sup>

	SBR® Repair	SBR® Lipocream
Skin condition: <sup>13</sup>	Very dry skin	Dry skin
Skin identical lipids <sup>8,13</sup>	Ceramides, fatty acids, cholesterol	Cholesterol, fatty acids
Lipid content <sup>13</sup>	70 %	38 %

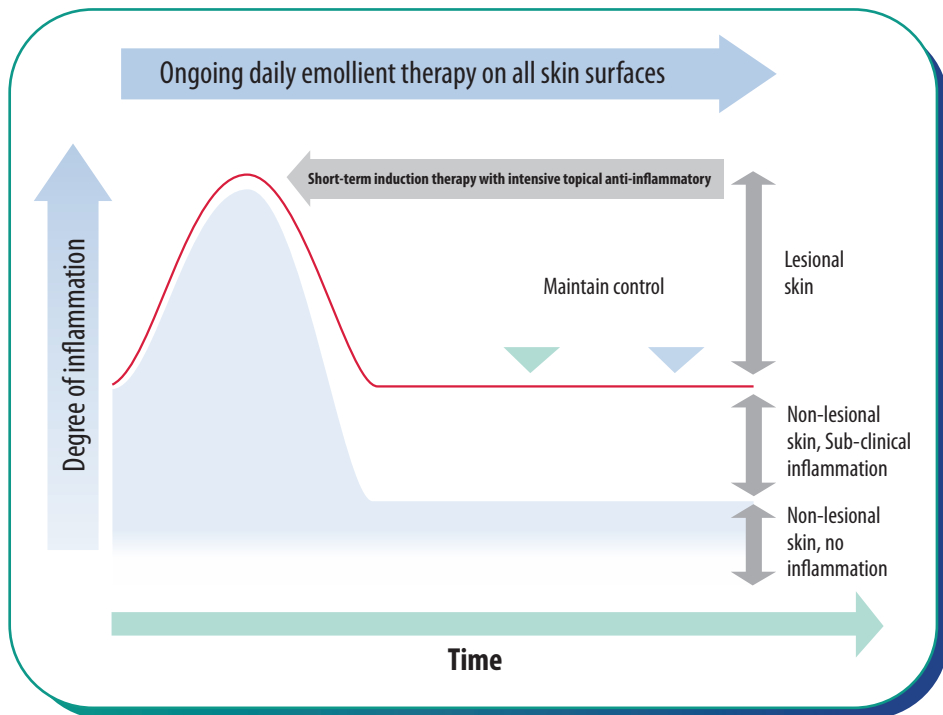
## Step 2: Control the flare

An initial flare is often treated with a topical corticosteroid.<sup>3,14</sup> Topical corticosteroids have anti-inflammatory action to treat the inflammation and symptoms associated with a flare. Long-term use with topical corticosteroids is not recommended, as they may thin the skin, may cause stretch marks or have other side effects.<sup>3,14</sup> It is essential that you follow your doctor's prescription and not use topical corticosteroids irresponsibly

**There are various options available for treating flares, but you or a family member have been prescribed PROTOPIC® to control flares. Your doctor will establish how to use the product based on your needs and may amend this as soon as your symptoms are under control.<sup>14,15</sup>**

## Step 3:

## Maintain control and prevent flares from occurring<sup>3,5,9,15</sup>



Adapted from Wollenberg A, et al, 2016<sup>3</sup> and Danby SG, et al, 2015<sup>5</sup>

Since symptoms of atopic eczema may flare up from time to time, treatment is planned with a long-term perspective.<sup>3</sup> Once the initial inflammation is under control, **PROTOPIC®** is applied twice-weekly to maintain control of atopic eczema and to prevent flare-ups<sup>15</sup>

# TIPS TO HELP PREVENT FLARE-UPS

## Avoid irritants wherever possible<sup>2</sup>



**Avoid soaps** and **bubble baths** as they can dry out the skin.  
Rather use a soap substitute or bath/shower emollient



**Use your emollient** daily



**Try** as much as possible **not to scratch**



**Wear cotton clothes** and try and **avoid** irritants such as **wool**



**Avoid getting too hot** or **too cold** as temperature changes can irritate the skin



**Avoid food allergens** and **pet dander** if you know that you are sensitive towards it

## HOW IS PROTOPIC® USED?

### To proactively control a flare from when the first tingle is noticed:<sup>15</sup>

**PROTOPIC®** is applied twice-daily until the symptoms resolve

### To maintain control and protect against a recurrent flare<sup>15</sup>

**PROTOPIC®** is applied once a day, twice-weekly e.g. on Mondays and Thursdays.

If signs of a flare reoccur, twice-daily treatment should be re-initiated. Your doctor will review your progress after 1 year, to determine if you need to continue with your treatment.

### There are two strengths of PROTOPIC®

(**PROTOPIC® 0.03 %** and **PROTOPIC® 0.1 % ointment**).

Your doctor will decide which strength is best for you



*Always use PROTOPIC® exactly as prescribed by your doctor*

# HOW TO APPLY PROTOPIC®



**PROTOPIC®** ointment should be applied as a thin layer to affected or commonly affected areas of the skin. It may be used on any part of the body, including the face, neck and flexure areas, except on mucous membranes. Do not cover the area where the ointment has been applied with a plaster<sup>15</sup>

Although your emollient must be used daily, **PROTOPIC®** and the emollient must not be applied within 2 hours of each other<sup>15</sup>

## What side effects can I expect when using PROTOPIC®?


A burning sensation, itching or redness of the skin is very common at the start of treatment. These symptoms are usually mild-to-moderate and generally disappear within one week of using **PROTOPIC®**<sup>16</sup>

These side-effects are less if the skin is well moisturised, so apply your moisturiser as often as you can



For further information, kindly ask your doctor or pharmacist, or refer to the approved package insert

 **Protopic®**  
tacrolimus 0,03%,  
0,1% ointment

# Protopic®

tacrolimus 0,03%,  
0,1% ointment

You have subscribed to receive digital communication from Adcock Ingram. Should you no longer wish to receive digital communication, please reply with OPT-OUT/UNSUBSCRIBE.

**DISCLAIMER:** This material was presented in digital format, it is not intended for copying or distribution and remains the propriety property of Adcock Ingram

To report an Adverse Event, e-mail [Adcock.AEReports@adcock.com](mailto:Adcock.AEReports@adcock.com) or call +27 11 635-0134 To request a copy of the current approved package insert or references, e-mail: [Helpdesk.MedicalAffairs@adcock.com](mailto:Helpdesk.MedicalAffairs@adcock.com)

**References:** 1. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Atopic Dermatitis [online] July 2016 [cited] May 2017; Available from URL: [https://www.niams.nih.gov/Health\\_Info/Atopic\\_Dermatitis/default.asp](https://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/default.asp). 2. Atopic Eczema. [online] [cited] May 2017; Available from URL: <http://www.patient.info/health/atopic-eczema>. 3. Wollenberg A, Oranje A, Deleuran M, et al, for the European Task Force on Atopic Dermatitis/EADV Eczema Task Force. EITAD/EADV Eczema task force 2015 position paper on diagnosis and treatment of atopic dermatitis in adult and paediatric patients. J Eur Acad Dermatol venereol 2016. DOI: 10.1111/jdv.13599. 4. Fleischer AB, Boguniewicz M. An Approach to Pruritus in Atopic Dermatitis: A Critical Systematic Review of the Tacrolimus Ointment Literature. J Drugs Dermatol 2010;9(5):488-498. 5. Danby SG, Cork MJ. A New Understanding of Atopic Dermatitis: The Role of Epidermal Barrier Dysfunction and Subclinical Inflammation. Derma 2010;1(2):33-46. 6. Di Nardo A, Wertz P, Giannetti A, et al. Ceramide and Cholesterol Composition of the Skin of Patients with Atopic Dermatitis. Acta Derm. Venereol. 1998;78(1):27-30. 7. Alizadehfar R. Skin Barrier Repair in the Management of Atopic Dermatitis. Skin Therapy Letter. [online] 2015 Dec 22 [cited 2017 February 10]; Available from URL: <http://www.skintherapyletter.com/wp/2010/6/2/1.html>. 8. Transedit Dermatology Training Programme. Products. Locobase Repair®. 9. Wollenberg A, Bieber T. Proactive therapy of atopic dermatitis – an emerging concept. Allergy 2009; 64: 276–278. DOI: 10.1111/j.1398-9995.2008.01803.x. 10. Kucharekova M, Schalkwijk J, Van De Kerkhof PCM, et al. Effect of a lipid-rich emollient containing ceramide 3 in experimentally induced skin barrier dysfunction. Contact Dermatitis. 2002;46(6):331-38. 11. Kucharekova M, Van De Kerkhof PCM, Van Der Valk PGM. A randomized comparison of an emollient containing skin-related lipids with a petrolatum-based emollient as adjunct in the treatment of chronic hand dermatitis. Contact Dermatitis. 2003;48(6):293-99. 12. Berardesca E, Barbareschi M, Veraldi S, et al. Evaluation of efficacy of a skin lipid mixture in patients with irritant contact dermatitis, allergic contact dermatitis or atopic dermatitis: a multicenter study. Contact Dermatitis. 2001;45:280-85. 13. SBR® Patient Information Leaflet (SBRPat02/30 Jan 2014); May 2015. Astellas Pharma (Pty) Ltd. 14. Kirsner RS, Heffernan MP, Antaya R. Safety and Efficacy of Tacrolimus Ointment Versus Pimecrolimus Cream in the Treatment of Patients with Atopic Dermatitis Previously Treated with Corticosteroids. Acta Derm Venereol 2010;90:58–64. doi: 10.2340/00015555-0748. 15. Protopic® 0.03 % and 0.1 % ointment approved package insert. February 2017. 16. Protopic 0.1 % Ointment. Package leaflet. Information for the user [online] 2016 June [cited] 2017 May; Available from URL: <http://www.medicines.ie/medicine/8852/PIL/Protopic-0.1-+-Ointment/>.

☞ PROTOPIC® 0,03 % Ointment. Each 1 g contains 0,3 mg of tacrolimus as tacrolimus monohydrate (0.03 %). Reg. No. A40/13.12/0219. ☞ PROTOPIC® 0,1 % Ointment. Each 1 g contains 1,0 mg of tacrolimus as tacrolimus monohydrate (0.1 %). Reg. No. A40/13.12/0231. Under licence from LEO Pharmaceutical Products, Ballerup, Denmark. For full prescribing information, refer to the package insert approved by the Medicines Regulatory Authority. 20200611039249.