

What you should know about Freederm Gel

The name of your treatment is Freederm. It is a translucent topical gel containing 4% w/w nicotinamide as the active ingredient. It also contains aluminium magnesium silicate, hypromellose, citric acid, polyoxyethylene lauryl ether, ethanol and water. The tube contains 25 g of Freederm.

Nicotinamide has an anti-inflammatory effect, which is helpful in the treatment of acne pimples and spots. Nicotinamide is not an antibiotic, it is related to an essential vitamin in our diet (Vitamin B₃).

(FREEDERM IS MADE FOR THE MARKETING AUTHORISATION HOLDER, DIOMED DEVELOPMENTS LTD, HITCHIN, HERTS, SG4 7QR, UK, AT AEROPAK, GREAT YARMOUTH, NORFOLK, NR31 0NU, UK.)

Freederm is used for the treatment of mild to moderate inflamed (angry) acne pimples and spots in all age groups.

Before you use Freederm Gel

This product is only for application to the skin.

Do not use Freederm if you are allergic (hypersensitive) to any of its ingredients (as listed above).

When using Freederm on the face, take care to keep it away from the eyes and mucous membranes, including those of the nose and mouth.

As is generally advisable if you have unusually sensitive skin and are applying any new treatment for the first time, it is a good idea initially to test the gel on a small area, and wait for 24 hours before using it on larger areas. This is especially important when treating the face.

There are no specific restrictions to using Freederm during pregnancy or breast feeding. However, although there are no known potential risks, as with any medicine caution should be exercised, particularly in the first three months of pregnancy. Ask your doctor or a pharmacist for advice.

How to use Freederm Gel

Use twice daily as follows: Cleanse the affected and surrounding skin thoroughly with soap and warm water. Gently dry and apply a thin film of Freederm to cover this area.

Possible side-effects

Although Freederm has been designed for use on all skin types including problem skin, side-effects can occur in rare cases. In a few susceptible individuals, it can be overly drying on the skin. If this is unacceptable, or causes irritation or peeling, try reducing the dosage to one application per day or every other day.

Allergic reactions such as itching (pruritus), redness (erythema), swelling, or burning sensations occur very rarely. If you experience these reactions, or any other side-effects not mentioned in this leaflet, or if you are in any doubt about the treatment, stop using the gel and tell your doctor or pharmacist.

How to store Freederm Gel

- This product should not be used after the expiry date stated on the pack.
- Always replace the cap tightly after use.
- Keep Freederm out of the reach and sight of children.
- Do not store above 25°C.

HEALTH EDUCATION INFORMATION

What Is Acne?

Acne is a skin disorder that occurs mainly on the face, back and chest. It affects a high proportion of both sexes, most commonly between the ages of 14 and 20, although it can last well into adulthood or even occur for the first time in adults. The early stages of acne often involve blackheads and whiteheads (doctors refer to these as 'comedones'). These can develop into angry, red or inflamed pimples or spots ('papules') which often contain pus (so-called 'pustules'). In a few extreme cases, groups of spots may become very inflamed and form cysts.

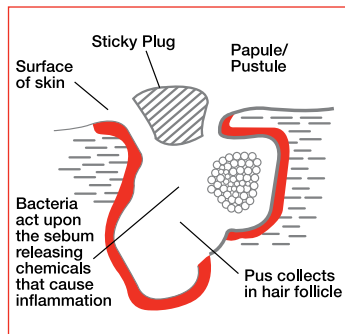
Acne is a very common skin complaint, affecting about 70% of teenagers. Whether you have just a few spots, or a hundred, it tends to be regarded as acne.

What Causes Acne?

Acne is not caused by eating too many sweets, chocolate or fatty foods (although healthy eating and a healthy lifestyle can help to alleviate it). Neither is it caused by not washing properly (although good personal hygiene is an important part of treatment). The exact cause of acne is not fully understood, but we do know that it involves the hair follicles in our skin and their associated oil-producing glands (the so-called pilosebaceous units). Often around the onset of puberty, hormones stimulate increased production of sebum (oil)

by these glands. Although normally this sebum flows out to lubricate the skin, when too much of it is produced it can become trapped within the pilosebaceous units where it forms a dark coloured plug or 'blackhead' where the opening is wide, or a light coloured plug or 'whitehead' where the opening is narrow.

Inflammatory acne begins when a common type of skin bacteria called *P. acnes* – which is normally harmless – starts to break down the trapped sebum. This process releases chemicals that cause inflammation in the surrounding skin, and leads to redness and the formation of 'angry' or inflamed-looking pimples and spots. These feel sore and tender, frequently contain pus and eventually burst open onto the skin before settling down. If the inflammation is deep in the hair duct, or if the spot is squeezed too early or aggressively, the pus can rupture into the skin and cause even more inflammation, and in extreme cases can even cause scarring.



Important tips when treating acne

- Take care to cleanse your skin thoroughly and regularly, but try not to clean too aggressively as this can make matters worse.
- Many acne patients find their skin becomes excessively dry. If this happens, ask your doctor or a pharmacist about suitable skin moisturisers.
- Carefully follow the instructions supplied with any medication you are using, as this will give you the best chance of clearing your condition.
- When using treatments applied to the skin, you will need to treat all the involved skin area, not just each individual spot.
- Try to avoid picking or severely squeezing your spots because this can make matters worse and lead to scarring.
- Persevere with treatment because it can take several weeks for the skin's normal repair process to work.
- For further independent help and advice contact the Acne Support Group www.stopspots.org.

Date last revised: July 2006

Distributed by DDD Limited, 94 Rickmansworth Road, Watford, Herts, WD18 7JJ, UK, on behalf of 'Frederm' Registered Trademark and Marketing Authorisation holder, Diomed Developments Limited.

Read these instructions carefully before use and keep for future reference.

Frederm[®] gel

Nicotinamide 4% w/w