

Freederm[®] gel

nicotinamide 4% w/w

Please read all of this leaflet carefully before using this product.

Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

In this leaflet:

1. What Freederm Gel is and what it is used for
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1. WHAT FREEDERM GEL IS AND WHAT IT IS USED FOR

- Freederm Gel is a skin treatment for inflamed pimples and spots.
- The medical term for this condition is mild to moderate inflammatory acne vulgaris. It involves inflamed pimples (papules) and spots containing pus (pustules), often with skin redness (erythema) and some tenderness. The condition occurs mainly on the face, back and chest.
- Freederm Gel is suitable for use by **adults, children and the elderly**.
- The **active ingredient** in this product is nicotinamide. This ingredient treats pimples and spots by its anti-inflammatory activity, which reduces swelling, redness and tenderness.
- Nicotinamide is not an antibiotic, it is related to an essential vitamin in our diet (Vitamin B₃).

2. BEFORE YOU USE FREEDERM GEL

Do not use Freederm Gel if you are **allergic (hypersensitive)** to nicotinamide or any of the other ingredients of Freederm Gel listed in Section 6.

Take care when using this product:

- Only apply it to your skin.
- When using it on your face, keep it away from your eyes, and avoid getting it inside your nostrils, on your lips or inside your mouth.
- Depending on how sensitive your skin tends to be, it may be a good idea initially to test the gel on a small area, and wait 24 hours before using it on larger areas. This is especially advisable if you have unusually sensitive skin or if you are treating the face (as generally applies when using any new treatment for the first time).
- If you have groups of spots that are very inflamed and painful causing lots of damage to your skin, you may have severe acne. Ask your doctor or pharmacist for advice about alternative treatments.

Using other medicines

Freederm Gel is not known to affect, or to be affected by, any other medicines.

Pregnancy and breast-feeding

There are no specific restrictions to using Freederm during pregnancy or breast-feeding. Vitamin B derivative requirements, such as nicotinamide, are increased during pregnancy and infancy. 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 pharmacist for advice before taking any medicine.

Driving and using machinery

Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE FREEDERM GEL

For adults, children and the elderly:

Apply the gel **twice daily** over and around the affected skin areas as follows:

- Wash the area.
- Gently pat the skin dry (avoid rubbing as this may aggravate the skin).
- Apply a thin film of gel, and gently massage it in.

Continue using the gel twice daily in this way for as long as necessary (unless irritation occurs - see Section 4). Depending on the severity of your acne, it can take several weeks for the skin's normal repair process to work before you see a real improvement.

If there is no improvement within 12 weeks, or if your condition gets worse at any stage, ask your doctor or pharmacist for advice.

If the product gets into the eyes or mouth

The product may cause irritation if it gets into the eyes or mouth. Rinse affected areas with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists tell your doctor or pharmacist.

If you forget to use this product

Do not worry if you occasionally forget to use this product, just carry on using it when you remember.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Although Freederm Gel has been specially designed for use on all skin types including problem skin, it can cause side effects, although not everybody gets them.

- Occasionally, susceptible individuals can experience local skin dryness. If this is unacceptable, or causes irritation or peeling, try applying the gel only once a day or every other day.
- Very occasionally, **allergic** reactions such as itching (pruritus), redness (erythema), swelling or burning sensations can occur.

Stop using this product and **tell** your doctor or pharmacist if any side effect gets serious, or you notice any other side effects not mentioned in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FREEDERM GEL

- Keep it out of the reach and sight of children.
- Always replace the cap tightly after use.
- Do not store the product above 25°C.
- Do not use after the expiry date shown on the tube and carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION ABOUT FREEDERM GEL

What Freederm Gel contains:

The **active ingredient** is **nicotinamide** (4% w/w).

The **other ingredients** are aluminium magnesium silicate, hypromellose, citric acid, macrogol lauryl ether, ethanol and purified water.

What Freederm Gel looks like and contents of the pack

- The product is a translucent gel.
- The product is available in tubes containing 10g of gel.

The Marketing Authorisation holder is

Diomed Developments Ltd, Tatmore Place, Gosmore, Hitchin, Hertfordshire, SG4 7QR, UK.

The Manufacturer is Aeropak,

Viking Road, Great Yarmouth, Norfolk, NR31 0NU, UK.

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 red or inflamed pimples or spots ('papules') which often contain pus (so-called 'pustules'). In a few severe 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.

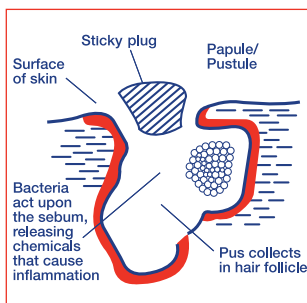
What Causes Acne?

Acne is not caused by eating too many sweets, chocolate or fatty foods (although healthy eating and a healthy lifestyle is good

for your general health). Neither is it caused by not washing properly (although a good skin care routine 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.



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This is a service provided by the Royal National Institute of Blind People (RNIB).