

# NOVADAC ONCE DAILY GEL

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using NOVADAC ONCE DAILY GEL?

NOVADAC ONCE DAILY GEL contains the active ingredients clindamycin (as phosphate) and benzoyl peroxide.

NOVADAC ONCE DAILY GEL is used on the skin to treat acne.

For more information, see Section [1. Why am I using NOVADAC ONCE DAILY GEL?](#) in the full CMI.

### 2. What should I know before I use NOVADAC ONCE DAILY GEL?

Do not use if you have ever had an allergic reaction to NOVADAC ONCE DAILY GEL or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use NOVADAC ONCE DAILY GEL?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NOVADAC ONCE DAILY GEL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use NOVADAC ONCE DAILY GEL?

- The usual dose of NOVADAC ONCE DAILY GEL is an application of a thin layer of gel once daily in the evening.
- Wash the affected area and rinse with warm water then lightly pat dry the skin.
- Apply a thin layer of gel to the area of the skin that has acne and not just the individual spots.

More instructions can be found in Section [4. How do I use NOVADAC ONCE DAILY GEL?](#) in the full CMI.

### 5. What should I know while using NOVADAC ONCE DAILY GEL?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using NOVADAC ONCE DAILY GEL.</li><li>• If you become pregnant while using this medicine, tell your doctor immediately.</li><li>• Avoid excessive exposure to sunlight.</li><li>• Tell your doctor if you feel that NOVADAC ONCE DAILY GEL is not helping your condition.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• You should not use NOVADAC ONCE DAILY GEL to treat any other complaints unless your doctor tells you.</li><li>• You should not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how NOVADAC ONCE DAILY GEL affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store NOVADAC ONCE DAILY GEL in the refrigerator.</li><li>• Once it is opened, store in the refrigerator for up to 2 months.</li></ul>

For more information, see Section [5. What should I know while using NOVADAC ONCE DAILY GEL?](#) in the full CMI.

### 6. Are there any side effects?

Serious side effects can include: allergic reactions; nausea, vomiting, diarrhoea, including bloody diarrhoea, stomach pain; skin reactions, discoloration of the skin; raised itchy rash (hives).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NOVADAC ONCE DAILY GEL

Active ingredient(s): *Clindamycin 1% w/w (as phosphate) and benzoyl peroxide 5% w/w*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NOVADAC ONCE DAILY GEL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NOVADAC ONCE DAILY GEL.**

### Where to find information in this leaflet:

- [1. Why am I using NOVADAC ONCE DAILY GEL?](#)
- [2. What should I know before I use NOVADAC ONCE DAILY GEL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NOVADAC ONCE DAILY GEL?](#)
- [5. What should I know while using NOVADAC ONCE DAILY GEL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using NOVADAC ONCE DAILY GEL?

NOVADAC ONCE DAILY GEL contains the active ingredients clindamycin and benzoyl peroxide.

Clindamycin is an antibiotic, which prevents the growth of bacteria which is involved in acne.

Benzoyl peroxide acts to reduce comedones (blackheads and whiteheads). It is also effective at killing the bacteria, which are involved in acne, and makes the skin less oily.

Your doctor may have prescribed NOVADAC ONCE DAILY GEL for another purpose. Ask your doctor if you have any questions about why NOVADAC ONCE DAILY GEL has been prescribed for you.

NOVADAC ONCE DAILY GEL is for use by adults and adolescents (aged 12 years and above) with acne.

NOVADAC ONCE DAILY GEL is not addictive.

NOVADAC ONCE DAILY GEL is only available with a doctor's prescription.

## 2. What should I know before I use NOVADAC ONCE DAILY GEL?

### Warnings

#### Do not use NOVADAC ONCE DAILY GEL if:

- if you have an allergy to NOVADAC ONCE DAILY GEL or any of the ingredients in NOVADAC ONCE DAILY GEL listed at the end of this leaflet.

- Always check the ingredients to make sure you can use the medicine.
- if you have a known sensitivity to benzoyl peroxide, clindamycin or lincomycin.
- you have or have ever had:
  - regional enteritis (inflammation of the small intestine),
  - colitis (inflammation of the large intestine),
  - ulcerative colitis (inflammation which may be due to the presence of ulcers).
- antibiotic associated colitis (inflammation which may be associated with the past use of antibiotics).

### Check with your doctor if you:

- have any other medical conditions.
- Take any medicine for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not apply NOVADAC ONCE DAILY GEL to the breasts before breastfeeding.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are using other creams, ointments or lotions or taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. These include:

- medicated or abrasive soaps and cleansers;
- chemical peels; and
- cosmetic products that have a strong drying effect.

**Some medicines may interfere with NOVADAC ONCE DAILY GEL and affect how it works. These include:**

- erythromycin;
- clindamycin;
- lincomycin;
- benzoyl peroxide;
- tretinoin, isotretinoin or tazarotene;
- salicylic acid;
- topical sulfonamide-containing products (e.g., Flamazine burn cream) as this may cause skin and

facial hair to temporarily change colour (yellow /orange) and

- alcohol.

These medicines may have a cumulative irritant effect or affect how well NOVADAC ONCE DAILY GEL works. You may need to use different amounts of your medicine or you may need to use different medicines. Your doctor will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and how these affect NOVADAC ONCE DAILY GEL.**

#### 4. How do I use NOVADAC ONCE DAILY GEL?

**It is important to use NOVADAC ONCE DAILY GEL exactly as your doctor has told you.** Directions given to you by your doctor may differ from the information contained in this leaflet. If you do not understand the instructions on the box, tube or this leaflet, ask your doctor or pharmacist for help.

**NOVADAC ONCE DAILY GEL is for application to the skin only.**

Wash the affected area thoroughly and rinse with warm water. Lightly pat dry the skin. Remove make-up thoroughly before applying the gel. After it has dried, you can use non-greasy make-up.

**How much to use:**

- Apply a thin film of gel to all of the areas of the skin which have acne, not just the individual spots.
- As a guide, one fingertip (the amount of gel squeezed from the tube which reaches from the tip of your finger to the first joint) is enough to cover the face.
- Two and a-half fingertips of gel will cover your face and back.
- If the gel does not rub into your skin easily, you are using too much.
- Wash your hands after applying the gel.
- It may take 4-6 weeks before you see the full effects of NOVADAC ONCE DAILY GEL on your acne.
- Use NOVADAC ONCE DAILY GEL for as long as your doctor tells you to.
- Do not use NOVADAC ONCE DAILY GEL for more than 11 weeks unless your doctor tells you to.
- If you use NOVADAC ONCE DAILY GEL less often than you should, it may not work as well, and your skin problem may not improve.
- Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

#### **When to use NOVADAC ONCE DAILY GEL**

The usual dose is to apply NOVADAC ONCE DAILY GEL is once daily in the evening.

#### **If you forget to use NOVADAC ONCE DAILY GEL**

If it is almost time for your next application, skip the application you missed and apply NOVADAC ONCE DAILY GEL when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your gel as you would normally.

#### **Do not apply a double dose to make up for the dose you missed.**

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

#### **If you use too much NOVADAC ONCE DAILY GEL**

If you swallow NOVADAC ONCE DAILY GEL, you may need urgent medical attention.

Excessive application of NOVADAC ONCE DAILY GEL may result in severe skin irritation e.g., dermatitis, peeling and dryness.

#### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**).
- contact your doctor.
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

#### 5. What should I know while using NOVADAC ONCE DAILY GEL?

##### **Things you should do**

Tell your doctor(s) who is treating you that you are using NOVADAC ONCE DAILY GEL.

If you feel that NOVADAC ONCE DAILY GEL is not helping your condition, tell your doctor.

Tell your doctor if for any reason, you have not used NOVADAC ONCE DAILY GEL exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using NOVADAC ONCE DAILY GEL, tell your doctor.

If you are breastfeeding while using NOVADAC ONCE DAILY GEL, tell your doctor.

##### **Call your doctor straight away if you:**

- **develop stomach cramps or diarrhoea that does not improve or is severe.** Antibiotics may cause a condition that results in severe diarrhoea and stomach cramps. Although this is unlikely to happen with antibiotics applied to the skin, if you develop stomach cramps or diarrhoea that does not improve or is severe, stop using NOVADAC ONCE DAILY GEL and contact your doctor immediately.

## Things you should not do

- Do not give your medicine to anyone else, even if they have the same condition as you.

## Things to be careful of

- Keep NOVADAC ONCE DAILY GEL away from your lips, eyes, mouth and other mucous membranes.
- Do not apply to any irritated areas of your skin; for example, if you have cuts, grazes, sunburn or eczema.
- Be careful not to use too much on your neck or other sensitive areas of the skin.
- Avoid excessive exposure to sunlight. Sunlamps should not be used. Avoid using it at high altitudes or where the ground is snow-covered. When exposure to sunlight cannot be avoided, use a sunscreen product and wear protective clothing.
- NOVADAC ONCE DAILY GEL may bleach hair and coloured fabrics, such as clothing, towels and bed linen. Be careful to avoid contact of NOVADAC ONCE DAILY GEL with hair and coloured fabrics.
- Do not use occlusive (air or water-tight) dressings on areas treated with NOVADAC ONCE DAILY GEL unless necessary. Using occlusive dressing may increase irritation.

## Driving or using machines

Be careful before you drive or use any machines or tools until you know how NOVADAC ONCE DAILY GEL affects you.

## Looking after your medicine

- NOVADAC ONCE DAILY GEL is to be stored in the refrigerator until it is opened.
- Once opened, keep NOVADAC ONCE DAILY GEL stored in the refrigerator and discard 2 months after opening.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Skin-related</b></p> <p><u>At site of application:</u></p> <ul style="list-style-type: none"> <li>Dry skin</li> <li>Skin peeling</li> <li>Redness of your skin, especially during the first few weeks of use. These side effects are generally mild.</li> </ul> <p><u>At the site of application:</u></p> <ul style="list-style-type: none"> <li>Skin burning sensation</li> <li>Itching</li> <li>Skin pain</li> <li>Sensitivity to sunlight</li> </ul> <p><u>At the site of application:</u></p> <ul style="list-style-type: none"> <li>Tingling (paraesthesia)</li> <li>Red, itchy skin, rash (dermatitis, erythematous rash)</li> <li>Worsening of acne</li> </ul> <p><b>Non-skin related</b></p> <ul style="list-style-type: none"> <li>Headache</li> </ul>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

## Serious side effects

Serious side effects	What to do
<p><b>Skin-related</b></p> <ul style="list-style-type: none"> <li>Allergic reactions</li> </ul> <p><u>At the site of application:</u></p> <ul style="list-style-type: none"> <li>Skin reactions, discoloration of the skin</li> <li>Raised itchy rash (hives)</li> </ul> <p><b>Stomach-related</b></p> <ul style="list-style-type: none"> <li>Nausea,</li> <li>vomiting,</li> <li>diarrhoea, including bloody diarrhoea,</li> <li>stomach pain.</li> </ul> <p><b>If you suffer severe burning, peeling or itching, or other effects not mentioned in this leaflet, you should stop using NOVADAC ONCE DAILY GEL and go back to your doctor for advice.</b></p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What NOVADAC ONCE DAILY GEL contains

<b>Active ingredient (main ingredient)</b>	Clindamycin 1% w/w (as phosphate) Benzoyl peroxide 5% w/w
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• carbomer 980</li><li>• dimeticone 100</li><li>• disodium lauryl sulfosuccinate</li><li>• disodium edetate</li><li>• glycerol</li><li>• silicone dioxide</li><li>• poloxamer</li><li>• purified water</li><li>• sodium hydroxide</li></ul>
<b>Potential allergens</b>	none

**Do not use this medicine if you are allergic to any of these ingredients.**

### What NOVADAC ONCE DAILY GEL looks like

NOVADAC ONCE DAILY GEL is a white to slightly yellow gel. NOVADAC ONCE DAILY GEL is available in lacquered membrane-sealed aluminium tubes fitted with a polyethylene screw cap containing 30 g.

AUST R 406130

### Who distributes NOVADAC ONCE DAILY GEL

Nova Pharmaceuticals Australasia Pty Ltd  
Suite 305, 10 Norbrik Drive,  
Bella Vista NSW 2153  
Toll free: 1800 002 171  
[www.novapharm.com.au](http://www.novapharm.com.au)

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