

## NOVATRETIN\*

*Acitretin*

10 mg, 25 mg capsules

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### What is in this leaflet

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**Please read this leaflet carefully before you start taking NOVATRETIN.**

This leaflet answers some common questions about NOVATRETIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NOVATRETIN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine. You may need to read it again.**

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### What NOVATRETIN is used for

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The active ingredient in NOVATRETIN capsules is acitretin, which belongs to a group of medicines called retinoids.

It is very similar to Vitamin A which is obtained from our diet and is vital for the normal growth and development of the body, especially the skin.

Psoriasis is a skin disease with thickened patches of red skin, often with silvery scales. NOVATRETIN is used to treat severe psoriasis and other severe skin disorders.

NOVATRETIN works to return skin to normal when problems with the normal development of

the skin are present, as in the case of severe psoriasis and some other skin disorders.

Your doctor may have prescribed NOVATRETIN for another reason. **Ask your doctor if you have any questions about why NOVATRETIN has been prescribed for you.**

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

#### ***Use in Children***

NOVATRETIN capsules should only be taken by children where alternative therapy cannot be used.

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### Before you take NOVATRETIN

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#### ***When you must not take it***

**Do not take NOVATRETIN if you are pregnant or you intend to become pregnant in the next 36 months.**

Any possibility that you may be pregnant must be ruled out by both yourself and your doctor before you start taking NOVATRETIN capsules. The result of a pregnancy test must be negative when performed within two weeks before beginning of NOVATRETIN treatment. NOVATRETIN is highly teratogenic, i.e. there is an extremely high risk of having a baby that is severely deformed.

**This means you must use effective contraception for one month before, during and 3 years after treatment with NOVATRETIN.**

**Do not take NOVATRETIN if you are breastfeeding.**

Breastfeeding must stop before NOVATRETIN treatment can start. Do not breastfeed while taking NOVATRETIN capsules.

**Do not take this medicine if:**

- you are taking vitamin A or preparations that contain vitamin A.
- you are taking tetracycline antibiotics, e.g. doxycycline.
- you are taking methotrexate.
- you have severe kidney or liver disease or abnormally high levels of fat in your blood.

**Do not take NOVATRETIN if you have an allergy to:**

- any medicine containing acitretin
- Vitamin A or other retinoids,
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching.

**Do not take it after the expiry date (EXP) printed on the back.** If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn or shows signs of tempering.**

**If you are not sure whether you should start taking NOVATRETIN, talk to your doctor.**

***Before you start to use it***

Tell your doctor if:

1. **you are currently pregnant, or you plan to become pregnant.**
2. **You are currently breastfeeding, or you plan to breast-feed.**
3. **you have allergies to:**
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.
4. **you have, or have had, the following medical conditions:**
  - diabetes (or family members with diabetes)
  - liver disease

**If you have not told your doctor about any of the above, tell them before you start taking NOVATRETIN.**

***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking NOVATRETIN.**

Some medicines may interfere with NOVATRETIN. These include:

- tetracycline antibiotics
- methotrexate
- phenytoin
- the 'mini-pill', a low-dose progestogen oral contraceptive
- vitamin A, or preparations that contain vitamin A

These medicines may be affected by NOVATRETIN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NOVATRETIN.

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**How to take NOVATRETIN**

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**Always take NOVATRETIN exactly as your doctor or pharmacist tells you to.**

The directions given may differ from information contained in this leaflet.

***How much to take***

Your doctor will determine exactly how many NOVATRETIN capsules to take each day for your condition.

This will be matched especially to your needs and your bodyweight and whether you develop any side effects.

The starting dose is usually either 25 mg (1 x 25 mg capsule) or 30 mg (3 x 10 mg capsules) per day for 2 to 4 weeks. Your dose will probably then be adjusted by your doctor when it is known how you respond to NOVATRETIN capsules.

The initial signs of improvement may be seen in the first week but, more often, after 2 or 3 weeks. It may take 2 to 3 months until the full effect is seen.

Affected skin areas will either peel off or steadily clear. Sometimes more redness or itching may be present at first, but this will normally improve as treatment continues.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.** If you take the wrong dose, NOVATRETIN may not work as well and your problem may not improve.

### ***How to take it***

NOVATRETIN capsules should be taken whole, preferably once daily with meal, or with a glass of milk

### ***When to take it***

**Take NOVATRETIN at about the same time each day.** Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take the capsules.

**Female patients should wait until the 2nd or 3rd day of their menstrual period before starting NOVATRETIN capsules.**

This helps to ensure that you are not pregnant before you start to take NOVATRETIN therapy.

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

A temporary increase in psoriasis is sometimes seen when first starting treatment

### ***If you forget to take it***

Take it as soon as you remember and then go back to taking it as you would normally.

However, if it is nearly time for your next dose, skip the dose you missed and take your next dose when you are supposed to.

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of unwanted side effects.

**If you are not sure what to do, ask your doctor or pharmacist.**

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## **While you are taking NOVATRETIN**

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### ***Things you must do***

**If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking NOVATRETIN.**

This medicine can cause birth defects. This means that you must use strict birth control for at least 1 month before you start NOVATRETIN, the whole time you are taking NOVATRETIN capsules and for at least 3 years after you finish taking NOVATRETIN capsules.

NOVATRETIN treatment should be started on the second or third day of your next normal menstrual period.

**If you become pregnant while taking this medicine, stop taking it immediately and inform your doctor. You must also tell your doctor immediately if you become pregnant in the 3 years following the end of treatment.**

**Inform your doctor if, for any reason, you have not taken NOVATRETIN exactly as prescribed.** Otherwise, your doctor may think this medicine was not effective and change your treatment unnecessarily.

**It is critical to keep all of your appointments with your doctor so your progress with NOVATRETIN therapy can be monitored regularly.** Your doctor may ask you to do some blood, liver function and other tests from time to time in order to check your progress and pick up any unwanted side effects.

**Inform your doctor if you take vitamin supplements that contain greater than 2500 IU of Vitamin A.** If you are unsure about this, please check with your doctor or pharmacist.

Consumption of alcohol should be avoided during treatment. Alcohol intake should also be avoided for 2 months after finishing treatment with NOVATRETIN.

### ***Things you must not do***

**Donation of blood by a patient being treated with NOVATRETIN is prohibited during and for three years after completion of treatment with NOVATRETIN.**

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

**Do not stop taking NOVATRETIN capsules or change the dose without first checking with your doctor.**

### ***Things to be careful of***

Normally NOVATRETIN capsules would not affect your ability to drive a car or operate machinery. However visual disturbances may occur while taking NOVATRETIN capsules. Make sure you know how you react to NOVATRETIN capsules before you drive a car, operate machinery or do anything else that might be dangerous if your vision is altered.

Wearing contact lenses during treatment and shortly after treatment with NOVATRETIN capsules may cause discomfort. NOVATRETIN capsules cause dry eyes so an eye lubricant, or artificial tears (available from your pharmacist) might be necessary. Otherwise you might need to compensate by wearing your glasses.

Avoid excessive sun exposure, and always apply sunscreen while taking NOVATRETIN capsules. Your skin may be more prone to sunburn while on NOVATRETIN.

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## **In case of overdose**

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***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much NOVATRETIN.**

**Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOVATRETIN.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

**Do not be alarmed by this list of possible adverse effects.** You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Common side effects can include:**

- dryness of the lips, mouth, nose, eyes and skin (either a moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin)
- drying and inflammation of mucous membranes
- thirst
- flushing
- difficulty producing tears
- intolerant of contact lenses
- itchiness, redness or rashes
- thinning or peeling of the skin that was not previously affected
- nail fragility or conditions
- eye infections
- abnormal liver tests
- increase in blood cholesterol
- muscle, joint or bone pain

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- headache
- nausea
- vomiting
- diarrhoea
- fatigue
- dizziness
- sleepiness
- abdominal pain
- gastritis
- heartburn
- strange hair texture or loss
- male breast enlargement
- more prone to sun burn
- changes in taste
- hay fever-like symptoms
- nose bleeds
- irregular menstrual bleeding
- swelling in limbs

**Tell your doctor as soon as possible if you notice any of the following symptoms:**

- changes in mood, including depression or aggression
- blurred vision or impaired night vision
- changes in hearing

These may be serious side effect of NOVATRETIN. You may need urgent medical attention.

**If any of the following happen, stop taking NOVATRETIN and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, mouth or thorax which may cause difficulty in swallowing or breathing
- hives
- fainting

These are very serious side effects. If you have them, you may have had a serious allergic reaction to NOVATRETIN.

**Tell your doctor if you notice any other effects.** Other adverse effects not listed above may also occur in some patients.

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## Storage and Disposal

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### *Storage*

**Keep NOVATRETIN in the blister pack until it is time to take them.** If you take the capsules out of the pack they may not keep well.

**Keep your capsules in a cool dry place** where the temperature stays at or below 25°C.

**Do not store in the bathroom or near a sink. Do not leave it in the car or on a windowsill.** Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### *Disposal*

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

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## Product description

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### *What it looks like*

NOVATRETIN 10 mg: Hard gelatin capsule containing a yellow powder with a white to off-white body and a brown cap printed in black with "A10" on the capsule body.

NOVATRETIN 25 mg: Hard gelatin capsule containing a yellow powder with a yellow to light yellow body and a brown cap printed in black with "A25" on the capsule body.

### *Ingredients*

#### Active ingredient(s)

Each NOVATRETIN 10 mg Capsule contains 10 mg of acitretin.

Each NOVATRETIN 25 mg Capsule contains 25 mg of acitretin.

#### Inactive ingredients

Novatretin capsules contain maltodextrin, sodium ascorbate, microcrystalline cellulose, gelatin, sodium lauryl sulfate, purified water, black printing ink (shellac glaze, iron oxide black (E172), propylene glycol (E1520)) and the colourants iron

oxide red (E172), iron oxide yellow (E172) and titanium dioxide.

Sulfur dioxide present as a residue in gelatin.

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## **Sponsor details**

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NOVATRETIN is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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## **Date of preparation**

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\*Novatretin is a registered trademark in New Zealand and other countries.