

PART III: CONSUMER INFORMATION

PrFINACEA®
azelaic acid gel

This leaflet is Part III of a three-part "Product Monograph" published when FINACEA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FINACEA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

FINACEA is used to treat rosacea (when the skin on the face is unusually red). FINACEA is for topical use only. This means that it is put on the skin.

What it does:

FINACEA is believed to reduce the production of substances known to contribute to inflammation (eg, cathelicidin, killikrein-5) thereby reducing the inflammation of rosacea.

When it should not be used:

Do not use FINACEA if you are allergic or hypersensitive to azelaic acid, propylene glycol or to any of the other ingredients in FINACEA. See the section titled "What the important non medicinal ingredients are" in this leaflet.

What the medicinal ingredient is:

azelaic acid gel, 15% w/w

What the important nonmedicinal ingredients are:

benzoic acid, disodium edetate, lecithin, polyacrylic acid, polysorbate 80, propylene glycol, medium-chain triglycerides, sodium hydroxide

What dosage forms it comes in:

FINACEA is available as gel (15% w/w) in tubes of 5 g, 30 g and 50 g.^b

^b Not all presentations may be available in Canada.

WARNINGS AND PRECAUTIONS

BEFORE you use FINACEA, talk to your doctor or pharmacist if:

- you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.

Children and Adolescents:

The safety and effectiveness of FINACEA in children and adolescents has not yet been established.

INTERACTIONS WITH THIS MEDICATION

There have been no formal studies evaluating the interaction of FINACEA with other drugs.

PROPER USE OF THIS MEDICATION

Usual adult dose:

Before applying FINACEA, the skin should be thoroughly cleaned with water or with a mild skin-cleansing agent. Pat dry with a soft towel before applying FINACEA.

Apply FINACEA sparingly to the affected skin areas twice a day, in the morning and evening, and rub it gently into the skin. About one finger-tip length (i.e. 2.5 cm or 1 inch) of gel squeezed from the tube is sufficient for your entire face. Avoid contact with the eyes, since it might irritate them.

In case of accidental contact of FINACEA with the eyes, inside of the nose, or mouth, wash your eyes, nose or mouth immediately with large quantities of water. If your eyes continue to hurt, tell your doctor.

If your skin becomes irritated, you should either:

- reduce the amount of FINACEA you apply each time; or
- apply it only once a day; or
- stop treatment for a few days.

Always wash your hands after using FINACEA.

Do not cover the treated area with dressings. Avoid alcoholic cleansers, tinctures and astringents, as well as abrasives and peeling agents.

Medication-free cosmetics or cosmetics which do not cause acne may be applied after FINACEA has dried.

Make sure very young children do not touch the treated area of your skin because of the mild irritant effect of FINACEA.

The length of time for which FINACEA must be used varies from person to person and also depends upon the severity of rosacea when you start treatment.

You should see a distinct improvement after about four to eight weeks. FINACEA should be used only as prescribed by your doctor.

If you have rosacea, you should avoid spicy foods, hot foods and drinks, and alcoholic drinks, since these may make rosacea worse. You should also use only mild skin-cleansing products to wash your face.

FINACEA will not affect your ability to drive and use machines.

Overdose:

FINACEA is for use on the skin only. If you apply too much and your skin becomes irritated, talk with your doctor. You may be instructed to start using less FINACEA less frequently, or to stop using FINACEA altogether until the irritation goes away.

Missed dose:

Do not use increased amounts of FINACEA to make up for a dose that you missed. Continue with your usual dosing schedule.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, FINACEA can have side effects. Skin irritation may occur, usually at the start of treatment. Common undesirable side effects include burning/stinging/tingling or itching sensations, reddening, skin dryness and scaling. Allergic skin reaction and infection of the hair follicle are uncommon side effects. In the majority of cases, the irritation symptoms are mild and go away over the course of treatment.

In very rare cases, allergic skin reactions may occur to azelaic acid or any of the nonmedicinal ingredients.

The following additional side effects have been observed outside of clinical trials:

- Hypersensitivity, which may occur with one or more of the following side effects: rapid swelling under the skin, eye swelling, swelling face, shortness of breath
- Hives

No serious side effects related to the use of FINACEA have been reported.

If you see any unusual changes in your skin colour, you should see your doctor.

If you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking FINACEA, contact your doctor or pharmacist.

HOW TO STORE IT

Store FINACEA at room temperature (15 – 30°C). Keep FINACEA out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701D
 - Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number and e-mail address.

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Last revised: May 17, 2016

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