



CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This leaflet answers some of the common questions about NATRAGEN®. 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 possible risks of you using NATRAGEN® against the benefits it can have for you. If you have any concerns about using NATRAGEN® talk to your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What NATRAGEN® is used for?

NATRAGEN® contains the natural hormone and active ingredient estradiol. This form of estradiol is identical to the estradiol produced by the ovaries of women. Estradiol plays an important role in female physical development, reproduction, maintenance of bone, energy levels and general well-being. During and after the menopause the production of sex hormones by the body decreases. Women may then suffer from complaints such as hot flushes, night sweats and vaginal irritation due to dryness. NATRAGEN® is used for the short-term relief of these menopausal complaints. It can also relieve these symptoms in women who have had their ovaries removed. Relief of symptoms usually starts within a few weeks, but optimal results are obtained after three months of treatment. The skin readily absorbs estradiol and NATRAGEN® is a simple and effective means of getting estradiol into the bloodstream.

Prior to using NATRAGEN®

NATRAGEN® is only for use in women. NATRAGEN® cream should not be used if you are allergic to estradiol, NATRAGEN® or any of the ingredients contained within NATRAGEN®. These are listed at the end of this leaflet. This product contains almond oil. Do not use NATRAGEN® if you have cancer especially breast cancer, kidney disease, are pregnant, lactating or have high calcium levels in the blood. If you have heart disease, high blood pressure or liver disease make sure your doctor is aware of these conditions before use as NATRAGEN® may not be appropriate for you. Check with your doctor or pharmacist if you are unsure about whether you have any of these conditions before starting NATRAGEN®. If you are taking other medications check with your doctor or pharmacist before starting NATRAGEN®.

Do not use NATRAGEN® after the expiry date which is printed on the base (crimp) of the tube. If you use this medicine after the expiry date has passed, it may not work as well. Do not use NATRAGEN® if the foil seal at the top of the tube is damaged or broken. NATRAGEN® is not indicated for use in children or males.

How to use NATRAGEN®

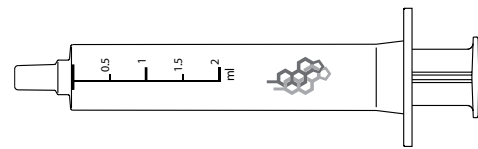
Your doctor will explain how to apply NATRAGEN®. Follow all directions exactly as they are explained. If you are unclear talk to your doctor. The dose of NATRAGEN® will be determined for you by your doctor. This dose is specific to your requirements and should not be varied unless directed to do so by your doctor. The recommended starting dose of NATRAGEN® is 0.5 ml (1mg estradiol) applied once daily. You will need to return to your doctor at regular intervals so that the dose can be checked via a blood test.

Opening the tube

To open the tube remove the cap and peel off the foil seal. Dispose of the foil seal and replace the cap firmly after using the cream.

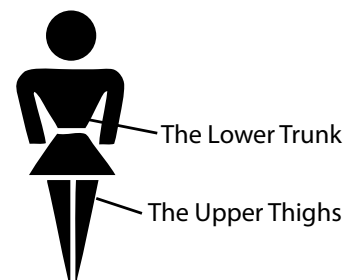
Measuring the correct dose of NATRAGEN® Cream

A measuring applicator (syringe style) in a sealed sleeve is enclosed in the NATRAGEN® box. The dose of NATRAGEN® is measured in millilitres (ml). The applicator is marked with 0.5ml graduations for dosing accuracy. Your doctor will have determined which dose is appropriate for you. To measure the correct dose of cream insert the tip of the applicator into the open nozzle of NATRAGEN® cream so that the nozzle and the shoulder of the applicator are in contact. GENTLY squeeze the base of the NATRAGEN® tube until cream reaches the open nozzle of the tube. At the same time slowly withdraw the plunger of the applicator. The cream will flow into the barrel of the applicator. Fill to the required dose. For example: a 1ml dose of NATRAGEN® (2mg estradiol) needs the flat part of the plunger level with the 1ml mark. If there are any air bubbles in the measured dose fill slightly past the required dose mark then depress the plunger so that the excess cream flows back into the tube. Stop at the required dose mark. Remove the applicator from the nozzle of the tube and replace the cap firmly on the tube. Depress the plunger of the applicator containing the dose of NATRAGEN® directly onto the skin (lower trunk or upper thigh). Massage the cream into the skin until absorbed. Rinse the applicator in warm water after use and replace in box with NATRAGEN® estradiol cream ready for the next day's application. Each 1ml of NATRAGEN® contains 2mg of estradiol.



Where to apply NATRAGEN® cream

Always apply NATRAGEN® cream to clean dry flat areas of skin. The best area to use NATRAGEN® is either to the lower trunk (abdomen) or upper thigh. The surface area of application should not exceed 200 square cms (8 square inches) or approximately an area the size of the palms of two hands. No perfume, deodorant or moisturising creams or gels should be used on the area because this may interfere with NATRAGEN® from being absorbed. Never apply the cream to broken or damaged skin. Do not use NATRAGEN® on the genital area. NATRAGEN® cream should be applied at approximately the same time each day. It is recommended that patients do not swim or shower until at least one hour after application of NATRAGEN® cream. Close skin contact with the area of application within an hour of application, by a partner or children should be avoided. This may result in the partner or child absorbing some estradiol through the skin contact.



If you miss a dose

If you forget to apply your cream, you should apply it as soon as you remember provided this is within 9 hours of your usual time of application.

Otherwise do not apply the cream until the next application is due. Missing a dose will not create an undue disruption to your treatment.



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If you use too much (overdose)

Because of the way NATRAGEN® is used, an unintentional overdose is unlikely.

If you think that you or anyone else may have used too much NATRAGEN®, immediately telephone your doctor or the local Poisons Information Centre for advice or go to the Accident and Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If NATRAGEN® is accidentally swallowed or eaten contact a doctor.

During NATRAGEN® use

Do's

Inform your doctor or pharmacist that you are using NATRAGEN® before starting any other prescribed medicine. Some medicines interact with other medications.

Tell all doctors, dentists and pharmacists who are treating you that you are using NATRAGEN®.

Have your hormone blood levels measured regularly by your doctor.

Do Not's

Do not give NATRAGEN® to anyone else, even if they have the same symptoms or condition as you.

Observe care when driving or operating machinery at the start of treatment using NATRAGEN® until you know how NATRAGEN® affects you. There is no evidence that NATRAGEN® will affect your ability to drive or to operate machinery.

Side-effects

Tell your doctor as soon as possible if you do not feel well while you are using NATRAGEN®.

All medicines can have side-effects in some people.

Sometimes they are serious: most of the time they are not.

Some side-effects may need medical treatment.

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- Skin irritation, for example rash or slight redness and itching of the skin where the cream has been applied. Any irritation will usually disappear within a few days. If it persists contact your doctor or pharmacist.
- Heaviness and tension in the breasts
- Headache
- Fatigue
- Nausea
- Dizziness
- Palpitations
- Edema (swelling)
- Weight increase
- Unscheduled or breakthrough bleedings.
- Skeletal pain
- Itching
- Muscle pain
- Nervousness
- Depression

Tell your doctor if you observe any other effects not listed above. If any of the above side-effects are experienced they are usually transient, however a lowering of the dose may be required if symptoms persist.

Do not use NATRAGEN® if you have any of the following:

- Family and personal history of cancer of the breast or uterus (womb)
- Endometriosis
- Undiagnosed vaginal bleeding
- Previous thrombo-embolic disorder (blood clots)
- Cardiovascular disease
- Thrombophlebitis
- Herpes gestationis
- Liver or kidney impairment
- Pregnancy and lactation
- Continual headache and migraine
- Know hypersensitivity to NATRAGEN® or any of its components

Product description

NATRAGEN® cream is a white opaque odorless cream in a sealed laminated tube. The crimp at the base of the tube has the batch number and expiry date imprinted on it.

The tube is boxed together with a consumer information sheet and a graduated measuring applicator.

Ingredients

Each 50 ml tube of NATRAGEN® contains 100 milligrams (100mg) of estradiol. Each 1ml dose delivers 2mg of estradiol. Other ingredients in the cream include cetomacrogol 1000, cetostearyl alcohol, almond oil, dl- α -tocopherol acetate (Vitamin E acetate), butylated hydroxytoluene, anhydrous citric acid, triethanolamine, Carbomer 940, B&J Phenonip® and purified water.

NATRAGEN® is available in a 50 ml sealed laminated tube.

Storage

Store below 25°C. DO NOT FREEZE.

Once opened, the contents of the tube should be used within 12 weeks.

Sponsor

HormoneSolutions.com

on behalf of Lawley Pharmaceuticals Pty Ltd

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