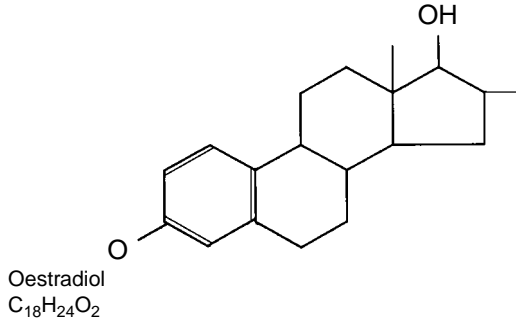


Natragen® Cream (Oestradiol)

Product Information

COMPOSITION: Oestradiol B.P.

CHEMICAL NAME: Estra-1,3,5,(10)-triene -3,17 B-diol



DESCRIPTION: Natragen contains the active ingredient oestradiol BP (micronised) a naturally occurring hormone, in a white vanishing - cream base. Contains dl- α tocopherol acetate (Vitamin E)

PHARMACOLOGY: Oestradiol is a naturally occurring oestrogenic hormone. Oestradiol is formed from steroid precursors in the ovarian follicles of premenopausal women, under the influence of the pituitary. In men and postmenopausal women oestrogens are formed in the adipose tissue of the adrenal glands and other organs; in pregnancy large amounts are produced by the placenta. Oestradiol is responsible for development and maintenance of the female sex organs, secondary sex characteristics and mammary glands. Functioning of aspects of the uterus and accessory organs, particularly the proliferation of the endometrium and cyclical changes to the cervix and vagina are under the influence of oestradiol. Progesterone complements the action of oestradiol for the complete biological function of the sex organs. Oestradiol is absorbed from the gastro-intestinal tract through the skin and mucus membranes. Transported via plasma proteins once absorbed oestradiol undergoes some entero-hepatic recycling and is rapidly metabolised by the liver to the less active oestrone and oestrone. It is excreted in the urine as glucuronide and sulphate esters together with a small percentage unchanged and also other metabolites. Elimination half - life of oestradiol in plasma is approximately 1 hour.

INDICATIONS: Natragen® is indicated for conditions of oestrogen deficiency, management of menopausal symptoms and prevention of postmenopausal bone loss. Menopausal and postmenopausal symptoms that oestrogen treat include vasomotor symptoms such as hot flushes and vaginal or vulval atrophy. Oestrogens are indicated in the management of postmenopausal osteoporosis.

CONTRAINDICATIONS: Natragen® is contraindicated in patients with

- family and personal history of carcinoma of the breast or endometrium
- Endometriosis
- Undiagnosed vaginal bleeding
- Previous thrombo-embolic disorder
- Cardiovascular disease
- Thrombophlebitis

- Herpes gestationis
- Liver impairment
- Pregnancy and lactation
- Non-hysterectomised women unless on concomitant progestogen therapy
- Know hypersensitivity to Natragen® or any of its components

PRECAUTIONS: Endometrial hyperplasia and cancer are well documented adverse effects from unopposed oestrogen supplementation in women with an intact uterus. The addition of a cyclic progestogen in combination with Natragen® is essential for these women. Natragen® is not recommended for patients with fibrocystic breast disease, ovarian cysts or uterine fibroids. Caution should be exercised when administering oestradiol to patients with heart failure, hypertension, reduced liver and kidney function, epilepsy or continual headache and migraine.

USE IN PREGNANCY: Oestrogens must not be used during pregnancy **Category B:** Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

As experience of effects of drugs in this category in humans is limited, results of toxicological studies to date (including reproduction studies in animals) are indicated by allocation to one of three subgroups:

Group B1: Studies in animals have not shown evidence of an increased occurrence of foetal damage.

ADVERSE REACTIONS: In some patients oestrogens can cause side effects all of which are of variable severity. More commonly nausea, breast tenderness, bloating, abdominal pain, breakthrough bleeding, aggravated migraine and headache, weight gain, depression, fatigue and irritability have been reported. Less common effects include fluid retention, increased blood pressure, increased incidence of blood clotting, increased appetite and tinnitus.

USUAL THERAPEUTIC DOSE: Natragen® provides 0.9mg of oestradiol per 1.5Gm (3cm) application. An applicator (with 1cm graduations) is provided with each tube of Natragen®.

Menopause Management: Apply 3cm (900mcg Oestradiol) cream daily or in divided doses. Dose may be increased or decreased as needed.

NOTE: Amount and duration of application must be tailored to individual requirements. Minimal dosing is optional in patient management.

PRESENTATION: Natragen® 0.06% cream contains 600mcg/g oestradiol BP in a 50Gm boxed tube.

STORAGE Store below 25°C DO NOT FREEZE.

POISONS SCHEDULE S4

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