

Genoderm

Coated tablets

Formula:

Each tablet contains 2.00 mg Cyproterone Acetate, 0.035 mg Ethinyl Estradiol and excipients s.q.

Indications :

Some manifestations of androgenization in women such as moderate and severe forms of acne, with or without seborrhea, intermediate androgenic alopecia and medium grade hirsutism.

Mechanism of action:

Cyproterone Acetate is a progestin characterized by an anti-androgen effect. In **Genobelle** it has the primary role of combating overactive sebaceous glands, so as to reduce the development of acne and other manifestations of androgenization.

As a progestin, it acts on the menstrual cycle and may cause it to be irregular. This effect can be avoided by associating an estrogen such as Ethinyl Estradiol, present in the formulation of **Genobelle**.

During the therapy with **Genobelle** it is advisable not to use hormone contraceptive compounds.

Cyproterone Acetate acts at a central and peripheral level by reducing the overactive sebaceous glands.

At a peripheral level it acts directly on the sebaceous gland, while at a central level it acts on the pituitary gland producing gonadotropins and ACTH with a direct impact on the sebaceous gland.

Dosage and method of administration:

To start treatment: Wait until your next menses. Start taking the first tablet of the pack orally on the first day of the menstrual cycle, that is, the first day of the menstrual bleeding. Then take 1 tablet each day for 21 consecutive days (3 weeks). After taking the 21 tablets make a 7-day pause during which you will have bleeding similar to your normal menses. After this 7-day break go on with a new pack.

In sum: 3 weeks of treatment, 1 week off.

Side effects:

Headaches, upset stomach, nausea, breast tenderness, breakthrough bleeding, weight changes, changes in the libido, depression, cloasma, dyspepsia, amenorrhea, anovulation, thromboembolic phenomena, In isolated cases there may be a reduced tolerance to contact lenses.

Contraindications:

Pregnancy, breastfeeding, severe disturbances of liver function, history of essential pregnancy-induced jaundice or severe pruritus gravidarum, Dubin-Johnson syndrome, Rotor syndrome or history of thromboembolic events (e.g. stroke), myocardial infarction, sickle cell anemia, current or treated carcinomas of the breast or endometrium, lipid metabolism disorders, history of herpes gestationis, history of aggravation of otosclerosis during an earlier pregnancy.

Reasons to stop the medication immediately:

First episode of migraine-type headaches, or frequent headaches of unusual intensity, acute vision disturbances, early signs of thrombophlebitis or thromboembolism; stenocardiac disorders, pre-planned surgery (6 weeks before the date schedule) and forced immobility (accidents, etc.), onset of jaundice (cholestasis) significant increase in blood pressure, or pregnancy.

Interactions:

Its action is diminished by barbiturates, Phenylbutazone, hydantoins, Rifampin and Ampicillin, Diabetics should adjust the doses of oral hypoglycemic agents or insulin.

Comments:

Before you start taking **Genobelle** you must undergo a thorough general examination and a careful gynecological check-up (including breasts) and rule out pregnancy.

Testing should include urine glucose tests and measurement of blood pressure.

The patient should undergo a medical examination every 6 months when therapy is prolonged.

Patients with impaired liver function should be undergo liver function tests at regular intervals.

The occurrence of hepatomas has been reported in rare occasions during prolonged treatment with hormone substances of the same type contained **Genobelle**.

Women who suffer from diabetes, hypertension, otosclerosis, multiple sclerosis, epilepsy, porphyria or tetany, as well as diabetes-prone women should be monitored closely.

Smoking cessation is recommended while on **Genobelle** therapy.

Genobelle is not indicated in male patients.

Presentation:

Blister pack containing 21 coated tablets.

Storage:

Store at room temperature, preferably below 30°C.
Keep out of the reach of children.