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GYNODIAN® DEPOT
BAYER MIDDLE EAST

Hormone combination for the treatment of climacteric complaints

Presentation

Ampoules of 1 ml

Store all drugs properly and keep them out of reach of children.

Composition

1 ml Gynodian Depot contains 200 mg prasterone enantate and 4 mg estradiol valerate in oily solution.

Properties

Gynodian Depot is a combination of estradiol valerate -an ester of the endogenous female estrogen which is well established as a suitable treatment of climacteric complaints in the female -and prasterone enantate- a substance used in this field of application for the first time. Both hormones complement each other in their actions. Gynodian Depot abolishes the autonomic disturbances which result from hormone deficiency, and has a favourable effect on psyche and vitality. The effect of Gynodian Depot usually begins to show a few days after the injection and lasts on the average 4 to 6 weeks.

Indications

Typical deficiency symptoms of the female climacteric or following oophorectomy or radiological castration for non-carcinomatous diseases (e.g. hot flushes, outbreaks of sweat, sleep disturbances, depressive moods, irritability, headaches, dizziness).

Furthermore. Gynodian Depot has a favourable influence on the irritable bladder a not infrequent occurrence in the climacteric- signs of cutaneous and mucosal involution (particularly in the genital region) which normally occur with advancing age, and on osteoporotic complaints.

Dosage and administration

Before starting the use of Gynodian Depot a thorough general medical and gynaecological examination (including the breasts) should be carried out.

As a precaution, control examinations should be conducted at intervals of about 6 months.

Like all oily solutions Gynodian Depot must be injected intramuscularly. Experience shows that the short -lasting reactions (urge to cough, coughing fits, respiratory distress) which occur in very rare cases during or immediately after the injection of oily solutions can be avoided by injecting the solution extremely slowly.

Usually 1 ml Gynodian Depot i.m. every 4 weeks. If the relief of symptoms is prolonged. The intervals between injections can be increased correspondingly.

As with all estrogen-containing preparations for the treatment of climacteric symptoms, treatment should he discontinued from time to time (approximately every 6 months) in order to verify the persistence of complaints requiring treatment. During treatment pregnancy must not occur (cf. “Special notes”)

Contraindications

Pregnancy, existing or suspected hormone-dependent tumours of the uterus or mammae, previous or existing liver tumours, endometriosis congenital disturbances of lipometabolism, otosclerosis with deterioration in previous pregnancy, thromboembolic processes.

Side effects

In rare cases, increased libido, a feeling of tension in the breasts, increase or decrease in body weight, uterine bleeding and signs of virilization (cf. “Special notes”) can occur.

Special notes

The patient should inform her doctor if she suffers from any of the following disorders: diabetes, high blood pressure, otosclerosis, multiple sclerosis, epilepsy, porphyria, tetany, chorea minor.

In all these cases, strict medical supervision is necessary.

Insulin and antidiabetic requirements may change.

If uterine bleeding occurs the patient must consult her doctor in order to clarify the cause.

During treatment pregnancy must not occur. Depending on the individual Situation, patients who

are still having menstrual periods should therefore practise contraception with non hormonal methods.

If during treatment with Gynodian Depot menstrual bleeding at the accustomed intervals fails to occur, pregnancy must be considered despite the protective measures. The treatment must then be interrupted until the situation has been clarified by differential diagnosis. Should increased hair growth on the face and legs or voice changes occur during Gynodian Depot treatment it is unlikely that this is causally related to the preparation, for experience shows that such signs of virilization can appear spontaneously in the climacteric. Nevertheless, patients who would be impeded in their professions by their singing or speaking voices being adversely affected should be kept under particularly close observation during treatment.

At the first indication of voice changes (easy fatigability of the voice. Hoarseness and huskiness) it is recommended that the therapy be discontinued, since in the individual case of an irreversible deepening of voice it will be impossible to ascertain whether a spontaneous virilization has occurred or not.

It has been concluded from epidemiological surveys that the use of oral estrogen/progestogen containing ovulation inhibitors is attended by an increased incidence of thromboembolic diseases. Although no such associations are suspected for injectable steroidal preparations of similar composition, one should keep the possibility of an increased thromboembolic risk in mind, particularly where there is a history of thromboembolic diseases or in the presence of severe diabetes with vascular changes or sickle- cell anaemia.

In rare cases benign and in even rarer cases malignant liver tumours, leading in isolated cases to life threatening intraabdominal haemorrhage have been observed after the use of hormonal substances such as those contained in Gynodian Depot. The doctor must therefore be informed of the occurence of unusual upper abdominal complaints which do not disappear spontaneously within a short time as it may then be necessary to withdraw the preparation.

There is a risk of endometrial hyperplasia under the administration of estrogens alone. This risk should be avoided preferably by the additional administration of a progestogen. The resultant transformation of the endometrium generally leads to shedding of the mucous membrane and withdrawal bleeding (as happens in normal menstruation).

The scientific brochure contains further information for the doctor.