Product Name: Cyclogynon sugar coated tablets

Composition:
Calendar – pack containing:

11 white tablets of:	Estradiol valerate	2 mg
10 light brown tablets of:	Estradiol valerate & Norgestrel	2 mg 0.5 mg

Medical group:
Hormones, estrogens, progesterone.

Properties:
The composition and effect of Cyclogynon are adjusted in such a way that provided the preparation is regularly, a menstrual cycle corresponding to physiological conditions is established. Furthermore, the characteristic subjective complaints due to hormone deficiency, occurring at the beginning of the climacteric, sometimes even at an earlier stage, are eliminated. These Complaints include above all hot flushes, tendency towards outbreaks of sweat, sleep disturbances, depressive moods, irritability, headaches, and dizziness.
Cyclogynon has also a favorable, 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.

Indications:
1. Pre- and postmenopausal symptoms (premenopausal syndrome);
2. Primary and secondary amenorrhea;
3. Irregularities of the menstrual cycle;
4. Deficiency symptoms after oophorectomy or radiological castration for non carcinomatous Diseases.

Contraindication:
Pregnancy, severe disturbances of liver function, jaundice or persistent itching during previous pregnancy, Dubin- Johnson syndrome, Rotor syndrome, previous or existing liver tumors, active deep venous thrombosis, thromboembolic disorders or a documented history of this conditions, sickle – cell anemia, existing or suspected hormone – dependent tumors of the uterus or mammae, endometriosis, severe diabetes with vascular changes, disturbances of lipometabolism, a history of herbes of pregnancy, otosclerosis with deterioration during pregnancy.

Dosage and administration:
Before starting a Cyclogynon a through general medical and gynecological Examination (including the breasts and a cytological smear of the cervix) should be carried out and pregnancy must be excluded. As a precaution, control examinations should be conducted at intervals of about six months during long – term treatment with Cyclogynon.
The pack contains 1 disc shape blister of 11white tablets followed by 10 light brown tablets. On the back of disc shape blister printed (start) at the blister of the first white tablet and there are arrows refer to the next tablet.
The first tablet must be taken on the (5th) day of the cycle (first day of menstrual bleeding = 1 st day of the cycle) tablet- taking is continued daily in the direction of the arrows (Preferably at the same time of the day) the tablets are to be swallowed whole with some liquid until all 21 tablets have been taken.
Following 21 days of tablet – taking there will be a tablet free interval of 7 days during which time – about 2 – 4 days after the last tablet was taken – a menstruation like with – drawl bleeding will occur. If not otherwise prescribed by the doctor, a new pack of cyclogynon should be started after the 7- free tablets days.
Patients with amenorrhea or bleeding at very irregular intervals can start cyclogynon treatment immediately up on medical prescription.
If the patient forgets to take the tablet at the usual time, she should take it within the following 12 hours.

Interactions:
The doctor should be informed if other medical preparations are taken
Regularly (e.g. . . Barbiturates, phenylbutazone, hydantoins, rifampicin, ampicillin) ,since they can impair the action of cyclogynon. The requirement for oral antidiabetics or insulin can change.

Side effects:
In rare cases, a feeling of tension in the breasts, gastric upsets, nausea, headaches, influence in body weight and libido, "unscheduled" bleeding can occur.

Reasons for immediate discontinuation of cyclogynon:
Occurrence for the first time of migrainous headaches or more frequent occurrence of unusually severe headaches, sudden perceptual disorders (e.g. Disturbances of vision or hearing), first signs of thrombophelebitis or Thromboembolic symptoms (for example, unusual pains in or swelling of the legs, stabbing pains on breathing or coughing for no apparent reason), a jaundice, onset of hepatitis, itching of the whole body, increase in epileptic Seizures, significant rise in blood pressure, pregnancy.

Pregnancy & Lactation:
If you are pregnant don't use the product, if you become pregnant stop using immediately, if you are a nursing mother don't use this product.

Special notes:
Cyclogynon is not contraceptive.
Where applicable, contraception should be practiced with non-hormonal methods (with the exception of the rhythm and temperature methods). If withdrawal bleeding at regular intervals of about 28 days 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.
If "unscheduled" bleeding occurs during the 3 weeks in which the tablets are being taken, the doctor should be consulted but tablet-taking should not be interrupted till then.
Pregnancy must be reliably ruled out before treatment of secondary amenorrhoea with cyclogynon is commenced.
The presence of prolactin-producing pituitary tumour should also be excluded because, according to the present state of knowledge, the possibility cannot be ruled out that macroadenomas increase in size when exposed to higher doses of estrogen for prolonged
Periods of time.
Epidemiological studies have suggested that hormone replacement therapy (HRT) may de associated with an increased relative risk of developing venous thromboembolism (VTE), i.e.
Deep venous thrombosis or pulmonary embolism. Risk/benefit should therefore be carefully weighted in consultation with the patient when prescribing HRT to women with a risk factor for VTE.
Generally recognized risk factors for VTE include a personal history, a family history (the occurrence of VTE in a direct relative at a relativity early age may indicate genetic disposition) and severe obesity. The risk of VTE also increases with age. There is no consensus about the possible role of varicose veins in VTE.
The risk of VTE may be temporary increased with prolonged immobilization, elective or posttraumatic sugary, or major trauma. Depending on the nature of the event and duration of the immobilization, consideration should be given to a temporary discontinuation of HRT.
The benefit of treatment with estrogen-containing preparation is undisputed and scientifically proven. Recently, however, the opinion has been expressed that the longterm use of unopposed estrogens during the climacteric may increase the incidence of endometrial carcinoma. Since this suspected risk cannot be entirely ruled out, endometrial hyperplasia should be avoided in unopposed estrogen treatment. This can be best achieved by the additional administration of a progesterone, as is the case anyway in the treatment with cyclogynon. In the second phase of the cycle, the progesterone component causes secretory transformation of the endometrium with subsequent withdrawal bleeding – as is the case in a natural cycle.
A meta-analysis from 51 epidemiological studies reported that there is a modest increase in the risk of having breast cancer diagnosed in women who have used HRT for more than five years. The findings may be due to an earlier diagnosis, the biological effects of HRT, or a combination of both. The relative risk increases with duration of treatment (by 2.3 % per year of use). This is comparable to the increased risk of breast cancer observed in women with every year of delay of natural menopause. The increased risk gradually disappears during the course of the first five years after cessation of HRT. Breast cancers found in women using HRT are more likely to be localized to the breast than those found in non-users.
Regular breast examination and, where appropriate, mammography should be carried out in women on HRT. Breast status should also be closely monitored in women with a history of, or known breast nodules or fibrocysitic breast disease.
In rare cases benign and in even rarer cases malignant liver tumours leading in isolate cases to life-threatening intraabdominal hemorrhage have been observed after the use of hormonal substances as those contained in cyclogynon. The doctor must therefore be informed of the occurrence of unusual upper abdominal complaints which do not disappear spontaneously within a short time.
The doctor should be informed if the patient suffers from the following disorders: diabetes, high blood pressure, varicose veins, otoscleresis, multiple sclerosis, epilepsy, porphyria, tetany, chorea minor. In all these cases, and also where there is a history of phlebitis, strict medical supervision is necessary.

Storage:
You must
1. Keep the product between 15-30° C.
2. Not use after expiry date.
3. Keep the medicine out of reach of children.
4. Consult your doctor or the pharmacist if you have any enquiry

Package:
11white tablets & 10 light brown tablets in disc shape blister printed (start) at the blister of the first white tablet and there are arrows refer to the next tablet.

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THIS IS A MEDICAMENTS

A medicament is a product but unlike any products.
A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctors prescription, the method of use and the instructions of the pharmacist who sold the medicament.
The doctor and the pharmacist are experts in medicines, their benefits and risks.
Do not by yourself interrupt the period of treatment prescribed.
Do not repeat the same prescription without consulting your doctor.

COUNCIL OF ARAB HEALTH MINISTERS **KEEP MEDICAMENTS OUT OF REACH OF CHILDDREN** ARAB PHARMACISTS ASSOCIATION

Produced by: IDM **International Drug Manufacturing - Syria - Aleppo**

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