

in or swelling of the legs, stabbing pains on breathing or coughing for no apparent reason), a feeling of pain and tightness in the chest, onset of jaundice, onset of hepatitis, itching of the whole body, increase in epileptic seizures, significant rise in blood pressure and pregnancy.

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 Estranor.

The requirement for oral antidiabetics or insulin can change.

Special notes

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 Estranor is commenced. The presence of a 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 period of time.

Epidemiological studies have suggested that hormone replacement therapy (HRT) may be 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 weighed 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 relatively 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 temporarily increased with prolonged immobilization, major elective or post-traumatic surgery, or major trauma. Depending on the nature of the event and the duration of the immobilization, consideration should be given to a temporary discontinuation of HRT. The benefit of treatment with estrogen-containing preparations is undisputed and scientifically proven.

Recently, however, the opinion has been expressed that the long term 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 progestogen, as is the case anyway in the treatment with Estranor. In the second phase of the cycle, the progestogen component causes secretory transformation of the endometrium with subsequent withdrawal bleeding

- as is the case in a natural cycle.

Ameta-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 increase 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 in non-users.

Regular breast examination and, where appropriate, mammograph 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 fibrocystic breast disease.

In rare cases benign and in even rare 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 Estranor. 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, otosclerosis, multiple sclerosis, elipepsy, prophyria, tetany, chorea minor. In all these cases, and also where there is a history of phlebitis, strict medical supervision is necessary.

Storage

Store between 15°C-30°C.

Protect from light & moisture.

Presentation

calendar-pack of 21 tablets.

Saffron

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ہدایات :-
ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
دوا کو 15°C سے 30°C درجہ حرارت کے درمیان رکھیں۔
نمی اور روشنی سے بچائیں۔
تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

RAM/06/08

Estranor Tablets

ایسٹرانار ٹیبلٹس

A two-phase preparation for the treatment of climacteric complaints and cycle disturbances

Important information, please read carefully!

Composition

Calendar-pack containing 11 tablets of 2 mg estradiol valerate each, plus 10 tablets of 2 mg estradiol valerate and 0.5 mg norgestrel each.

Properties

The composition and effect of Estranor are adjusted in such a way that, provided the preparation is taken 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 f tendency towards outbreaks of sweat, sleep disturbances, depressive moods, irritability, headach, dizziness. Estranor has also a favourable influence on the irritable bladder- an 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

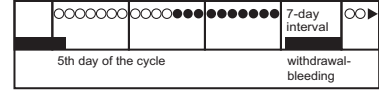
Pre- and postmenopausal symptoms (perimenopausal syndrome): primary and secondary amenorrhoea; irregularities of the menstrual cycle, deficiency symptoms after oophorectomy or radiological castration for noncarcinomatous diseases.

Dosage and administration

Before starting Estranor a thorough general medical and gynaecological 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 6 months during longterm treatment with Estranor. The pack contains an adhesive disc marked with the days of the week. After removing the protective foil the round disc should be stuck onto the front side of the tablet pack, so that the day of the week on which tablet-taking starts is directly under the section marked "Start", for example, if the first tablet is to be taken on a Wednesday, the "Start" section should be lined up with a day marked "Wed". Each tablet is thus marked with the corresponding day of the week and one can see at a glance whether the tablet for that day has been taken or not.

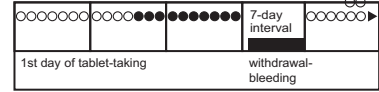
Tablet-taking is always started from the blister marked "Start and continued daily in the direction of the arrow. Until all 21 tablets have been taken. The tablets are to be swallowed whole with some liquid.

Estranor is started on the 5th day of the cycle (1st day of menstrual bleeding 1st day of the cycle).



●● Estranor

Patients with amenorrhoea or bleeding at very irregular intervals can start Estranor treatment immediately upon medical prescription



●● Estranor

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-drawal bleeding will occur. If not otherwise prescribed by the doctor, a new pack of Estranor should be started after the 7-day tablet-free interval, on the same day of the week as the previous one. It does not matter at what time of the day the patient takes her tablet, but once she has selected a particular time-preferably after her breakfast or evening meal-she should keep to it every day. If she forgets to take a tablet at the usual time, she should take it within the following 12 hours.

Side effects

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

Contraindications

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

Reasons for immediate discontinuation of Estranor

Occurrence for the first time of migrainous headache or more frequent occurrence of unusually severe headache, sudden perceptual disorders (e.g. disturbances of vision or hearing), first signs of thrombophlebitis or thromboembolic symptoms (for example, unusual pains