

## **REGISTERED PACKAGE INSERT**

### **SCHEDULING STATUS**

**S4**

### **PROPRIETARY NAMES AND DOSAGE FORMS**

## **PROGYNOVA 1 mg AND 2 mg**

Tablets

For estrogen therapy of climacteric complaints in the postmenopause

### **COMPOSITION**

Progynova tablets contain estradiol valerate (estra-1,3,5(10)-triene-3,17 $\beta$ -diol 17-valerate) 1,0 mg and 2,0 mg respectively.

### **PHARMACOLOGICAL CLASSIFICATION**

A. 21.8.1 Estrogens.

### **PHARMACOLOGICAL ACTION**

Progynova contains estradiol valerate, an ester of the endogenous female estrogen, which following regular oral administration eliminates the characteristic estrogen deficiency symptoms in the postmenopause or after oophorectomy or radiological castration for non-carcinomatous diseases.

### **INDICATIONS**

Climacteric complaints after the cessation of monthly bleeding or deficiency symptoms after oophorectomy or radiological castration for non-carcinomatous diseases, such as hot flushes, outbreaks of sweat, sleep disturbances, depressive moods, irritability, headaches, dizziness, bladder irritation, signs of muco-cutaneous involution.

### **CONTRA-INDICATIONS**

Pregnancy; severe disturbances of liver function; jaundice or persistent itching during a previous pregnancy; Dubin-Johnson syndrome; Rotor syndrome; previous or existing liver tumours; existing or previous thromboembolic processes (eg stroke, myocardial infarction); sickle-cell anaemia; existing or suspected hormone-dependent tumours of the uterus or mammae; endometriosis; severe diabetes with vascular changes; congenital disturbances of lipometabolism; otosclerosis with deterioration in previous pregnancies.

### **DOSAGE AND DIRECTIONS FOR USE**

Before starting Progynova a thorough general medical and gynaecological examination (including the breasts) should be carried out.

Unless otherwise prescribed by the doctor, 1 tablet Progynova 2 mg is taken daily after a meal. The tablets are to be swallowed whole with some liquid. After each 21-day regimen there must be a pause in tablet-taking of at least 1 week.

In the course of treatment, the doctor may decide to reduce the dose to 1 tablet Progynova 1 mg daily.

Under this lower dose, too, a tablet-free interval of at least 1 week should be observed after each 21-day regimen.

As a general rule, Progynova treatment should be discontinued every 6 months in order to verify the persistence of complaints requiring treatment.

### **SIDE-EFFECTS AND SPECIAL PRECAUTIONS**

A feeling of tension in the breasts, gastric upsets, nausea and vomiting, headaches, increase in body weight, and uterine bleeding can occur.

The doctor should be informed if other medical preparations are taken regularly (eg barbiturates, phenylbutazone, hydantoins, rifampicin, ampicillin) since they can impair the action of Progynova.

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

Gynaecological check-ups should be carried out at about 6-month intervals.

The doctor should be informed if the patient suffers from the following disorders: diabetes, high blood pressure, varicose veins, otosclerosis, 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.

Not for use during pregnancy.

An increased incidence of endometrial uterine carcinoma, related to the continuous use of estrogens in the postmenopausal period has been reported. Since this suspected risk cannot be entirely ruled out, endometrial hyperplasia should be avoided in unopposed estrogen treatment, eg by the additional administration of a progestogen. It is in any case essential to adhere to the dosage scheme prescribed by the doctor, including the instructions regarding tablet-free intervals and length of treatment, and to keep the appointments made for gynaecological check-ups.

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 the one contained in Progynova. If severe upper abdominal complaints, liver enlargement or signs of intraabdominal haemorrhage occur, a liver tumour should be included in the differential-diagnostic considerations and, if necessary, the preparation withdrawn.

### **Reasons for the immediate discontinuation of Progynova**

Occurrence for the first time of migrainous headaches or more frequent occurrence of unusually severe headaches; sudden perceptual disorders (eg disturbances of vision or hearing); first signs of thrombophlebitis or thromboembolic symptoms (for example unusual pains 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; pending operations (six weeks beforehand) and immobilisation, for instance following accidents; onset of jaundice; onset of hepatitis; itching of the whole body; increase in epileptic seizures; significant rise in blood pressure.

Estradiol and other estrogens may cause amenorrhoea, depression, dizziness, gynaecomastia (main side-effect in the male), hypercalcaemia (if used in metastatic conditions such as breast cancer), nitrogen retention, oedema, skin rashes, sodium retention, and alterations in liver function.

High doses of estrogens may cause premature closure of epiphysis and depression of malignant neoplasms while low doses may stimulate the growth of malignant neoplasms.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

See "Side-effects and special precautions". Symptomatic treatment according to conventional methods.

**IDENTIFICATION**

Progynova 1 mg : Beige, lustrous coated tablets.  
Progynova 2 mg : Blue, lustrous coated tablets.

**PRESENTATION**

Progynova 1 mg : Blister packs of 21 coated tablets.  
Progynova 2 mg : Blister packs of 21 coated tablets.

**STORAGE INSTRUCTIONS**

Store below 30°C. For shelf-life, refer to imprint on the pack. Keep out of reach of children.

**REGISTRATION NUMBER**

Progynova 1 mg : B/21.8.1/16

**REFERENCE NUMBER**

Progynova 2 mg : G.2981 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

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**DATE OF PUBLICATION OF THE PACKAGE INSERT**

20 September 1982