**COMPOSITION**

The 28-day pack (Every-Day pack) contains 21 hormonal tablets, 6 tablets each with levonorgestrel (d-13-ethyl-17α-ethinyl-17β-hydroxy-4-gonen-3-one) 0.05 mg and ethinylestradiol (17α-ethinyl-estra-1,3,5(10)-triene-3,17β-diol) 0.03 mg, plus 5 tablets each with levonorgestrel 0.075 mg and ethinylestradiol 0.04 mg, plus 10 tablets each with levonorgestrel 0.125 mg and ethinylestradiol 0.03 mg, plus 7 non-hormonal tablets.

**PHARMACOLOGICAL CLASSIFICATION**

A. 21.8.2 Progesterones with estrogens.

**PHARMACOLOGICAL ACTION**

Logynon ED is a three-step preparation for oral contraception, the reliability of which is equal to that of the classical single-phase combined preparations.

The three-step dosage scheme conforms with the physiological pattern of the normal cycle, and the total steroid dose is lower in comparison with other currently available combined oral contraceptives. The estrogen/progestogen ratio varies during the cycle, the dosage being administered as a 6-day/5-day/10-day regimen in order to ensure good cycle control and to bring about distinct cyclical changes at the level of the endometrium and the vaginal epithelium. At the same time, however, ovulation is inhibited, and the cervical mucus remains impenetrable, thus providing reliable contraceptive protection.

When taken according to instructions, a menstruation-like bleeding is induced at regular intervals of approximately 28 days.

**INDICATIONS**

Oral contraception and the recognised gynaecological indications for such estrogen-progestogen combinations.

**CONTRA-INDICATIONS**

Pregnancy, severe disturbances of liver function, jaundice or persistent itching during a previous pregnancy, Dubin-Johnson syndrome, Rotor syndrome, hormone dependent neoplasms, previous or existing liver tumours, existing or treated cancer of the breast or the endometrium, existing or previous thromboembolic processes in arteries or veins and states which predispose to such diseases (eg
disturbances of the clotting system with a tendency towards thrombosis, certain heart diseases), sickle-cell anaemia, severe diabetes with vascular changes, disturbances of lipometabolism, a history of herpes of pregnancy, otosclerosis with deterioration during pregnancy.

Lactation, severe migraine or cerebrovascular insufficiency, recurrent cholestatic jaundice and undiagnosed vaginal bleeding.

Relative contra-indications include a history of diabetes mellitus, epilepsy, asthma, hypertension, depression, porphyria, or states in which fluid retention occurs.

**Reasons for the immediate discontinuation of Logynon ED**

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 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), immobilisation (for instance, following accidents). In all these cases there may be an increased risk of thrombosis. Further reasons for discontinuation are: onset of jaundice, onset of hepatitis, itching of the whole body, increase in epileptic seizures, significant rise in blood pressure, pregnancy.

**DOSAGE AND DIRECTIONS FOR USE**

Before starting Logynon ED, a thorough general medical and gynaecological examination (including the breasts) should be carried out and the family case history carefully noted. In addition, disturbances of the clotting system must be ruled out if any members of the family have suffered from thromboembolic diseases (e.g., deep vein thrombosis, stroke, myocardial infarction) already at a young age. Pregnancy must be excluded.

Periodic medical examinations are advisable during long-term treatment.

**Initial course**

The first course of Logynon ED is started on the first day of the menstrual period (day 1 of the cycle) from the red section of the pack by selecting the appropriate tablet for that day of the week (e.g., "Mon" for Monday). The tablet is swallowed whole with some liquid. Thereafter one tablet must be taken every day following the direction shown by the arrows. It does not matter at what time of the day the tablet is taken, but once the patient has selected a particular time, the tablet should be taken as near as possible at the same time each day.

**Subsequent courses**

After the last tablet has been taken from the first pack, tablet-taking is continued from a new pack on the very next day. The first tablet must again be taken from the red section of the calendar pack marked with the appropriate day of the week.

When taken according to instructions, a menstruation-like bleeding is induced at regular intervals of approximately 28 days.

Normally, a bleeding will occur while the tablets from the red section of the packs are being taken. If, in exceptional cases, bleeding fails to occur while the tablets from the red section are being taken, tablet-taking must provisionally be stopped and the doctor must be consulted.

If the patient starts Logynon ED during the latter part of the week, the very first cycle may be slightly shortened.

After delivery or abortion, or when switching from other hormonal contraceptives, the patient must follow the doctor's instructions.
An additional non-hormonal method of contraception (with the exception of the rhythm and temperature methods) should be employed during the first 14 days of the first treated cycle.

If the patient forgets to take a Logynon ED tablet at the usual time, she must take it within the next 12 hours at the latest. If more than 12 hours elapse from the time that she normally takes her tablet, the contraceptive protection in this cycle may be reduced. She must nevertheless continue to take the other tablets in the pack at the usual time, forgetting about the ones she has missed. At the same time, however, an additional, non-hormonal method of contraception (with the exception of the rhythm and temperature methods) must be employed until bleeding occurs. The tablet or tablets which she missed should not be taken at all.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The incidence of diseases of the circulatory system in women using combined oral contraceptives is significantly greater than those of controls, and the mortality is slightly increased. Coronary thrombosis, cerebrovascular accidents and venous thrombosis are more likely to occur in women aged 35 years or over, particularly if they have used the contraceptive for longer than 5 years, if they smoke, if they are obese or if they are hypertensive. Additional risk factors are diabetes, hypercholesterolaemia and familial hyperlipoproteinemia. However, the risk of mortality due to oral contraceptives in women under 35 who are in the high-risk group is in general far less than the risk of mortality due to pregnancy.

Prolonged amorrhoea following the use of oral contraceptives may occur. The incidence is not higher than in non-users. Caution is advised where oligomenorrhoea or amenorrhoea have occurred in the past.

Side effects such as nausea, vomiting, headaches, mood changes, breast tension, skin pigmentation, vaginal candidiasis, gall-bladder disease, gastro-intestinal irritation, poor tolerance of contact lenses, fluid retention, changes in libido, weight gain and hypertension may occur. Regular blood pressure checks, including a pretreatment level, are advisable.

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 Logynon ED. If severe upper abdominal complaints, liver enlargement or signs of intraabdominal haemorrhage occur, a liver tumour should be included in the differential-diagnostic considerations.

Surgery is more likely to be associated with an increased incidence of thrombotic side effects. Adequate precaution should be taken.

Under no circumstances should the oral contraceptive tablets be stopped without having adopted a satisfactory alternative method of contraception.

Logynon ED may only be taken under strict medical supervision in the case of diabetes or a tendency thereto, high blood pressure, varicose veins, a history of phlebitis, otosclerosis, multiple sclerosis, epilepsy, porphyria, tetany, chorea minor.

Intermenstrual bleeding is more likely to occur during the first few cycles of use. If intermenstrual bleeding occurs, pill-taking should not be interrupted as a slight bleeding will usually stop spontaneously. However, if the bleeding is heavy, similar to menstrual bleeding, then a thorough examination is indicated to exclude organic factors.

Interaction with other medicines and efficacy

The efficacy of the contraceptive pill may be decreased when it is administered concomitantly with other medicines such as the anti-epileptic agents, ampicillin, barbiturates and rifampicin, and in patients with very rare individual metabolic disturbances.

The requirement for oral antidiabetics or insulin can change.

With vomiting or diarrhoea, the absorption of oral contraceptives may be diminished and women should be advised to use additional methods of contraception at the time of such disorders. Mild laxatives do not
impair the action of tablets.

Oral contraceptive failure may occur with concomitant antibiotic therapy. For maximal protection, additional non-hormonal contraception should be recommended for the duration of antibiotic therapy and for seven days afterwards. Those on long-term antibiotic therapy need only take extra precautions for the first two weeks of antibiotic therapy.

Spotting and breakthrough bleeding are possible signs of diminished contraceptive effectiveness.

Effects on laboratory tests

Oral contraceptives may interfere with some laboratory estimations, in particular hormones, glucose tolerance, thyroid function, blood coagulation, serum triglycerides and liver function tests.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

Symptomatic treatment according to conventional methods.

IDENTIFICATION

6 small pale brown coated hormonal tablets, 5 small white coated hormonal tablets, 10 small ochre coated hormonal tablets, and 7 large white coated non-hormonal tablets.

PRESENTATION

Cartons with one or three calendar packs each containing 28 tablets.

STORAGE INSTRUCTIONS

In original packs at room temperature (below 25°C). Protect from light. Keep out of reach of children. For shelf-life refer to the imprint on the pack.

REGISTRATION NUMBER

N/21.8.2/113

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

Bayer (Pty) Ltd
Trading as Bayer Schering Pharma
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