NORIDAY 28 DAY
Norethisterone 0.35 mg tablet.

PRESENTATION
Norethisterone 0.35 mg tablets are white, round, flat with bevelled edges, 7/32” diameter, inscribed “SEARLE” on one side and “NY” on the other.

USES

ACTIONS
NORIDAY 28 DAY is a progestogen-only oral contraceptive. Although the mode of action of NORIDAY 28 DAY tablets has not yet been fully defined it is thought that alterations occur in the cervical mucus which inhibit the penetration of sperm, there is substantial inhibition of ovulation, and changes occur in the endometrium which inhibit implantation of the fertilised egg.

INDICATION
For oral contraception in women for whom oestrogens may not be appropriate.

DOSAGE AND ADMINISTRATION

Oral
The first tablet is taken on the FIRST DAY of menstrual bleeding. Thereafter, one tablet is taken continuously at the same time every day preferably in the early evening even during menstrual bleeding.

To provide added protection during the first cycle only, the patient should be instructed to use an additional method of contraception (with the exception of rhythm, temperature and cervical-mucus methods).

Omitted tablets
Tablets must be taken at the same time each day in order to maintain adequate hormone levels.

If one tablet is missed
If one tablet is missed and there is a delay of more than 3 hours after the normal time of taking it, it should be taken as soon as possible, with the next tablet being taken at the usual time even if it means taking two tablets on the same day. An additional method of non-hormonal contraception (with the exception of rhythm, temperature and cervical-mucus methods) should be used along with NORIDAY 28 DAY for the next 14 days, irrespective of bleeding.
If two or more tablets are missed

If two or more tablets are missed, NORIDAY 28 DAY should be discontinued immediately and a method of non-hormonal contraception should be used until menses has appeared or pregnancy has been excluded.

Note: This type of contraception is a little less reliable than the conventional “pill” and it is important to ensure that instructions with regard to administration are followed most carefully.

Missed Period(s)

See section entitled “Warnings and Precautions”.

### CONTRAINDICATIONS

As with all progestogen oral contraceptives, the following conditions should be regarded as contraindications:

- Current thromboembolic process.
- Cerebral vascular or coronary artery disease or history of such disorders.
- Known or suspected carcinoma of the breast or genital organs or a history of such cancers.
- Undiagnosed abnormal vaginal bleeding.
- Known or suspected pregnancy.
- Acute or severe chronic liver disease, liver tumors or history of such tumors.
- A history during pregnancy of idiopathic jaundice or cholestatic jaundice.
- A history during pregnancy of severe pruritus.
- Dubin-Johnson or Rotor syndrome.
- Disturbances of lipometabolism or severe arterial disease.
- A history of ectopic pregnancy.
- Hypersensitivity to any component of the product.

### WARNING AND PRECAUTIONS

As with all progestogen oral contraceptives, the following conditions should be regarded as warnings and precautions:

- Patients with conditions such as hypertension, migraine and cardiac dysfunction, ovarian cysts or a malabsorption syndrome require careful observation whilst on progestogen contraceptives.
- Acute renal failure, gallbladder disease and haemolytic uraemic syndrome and alterations in lipid metabolism have been associated with the use of oral contraceptives.
- A statistical association between the use of oral contraceptives and the occurrences of thrombosis, embolism, or haemorrhage has been reported. Patients on such treatments should be kept under regular surveillance in view of the possibility of development of such conditions as
thromboembolism. Risk of coronary artery disease in women taking oral contraceptives is increased by the presence of other predisposing factors such as cigarette smoking, hypercholesterolaemia, obesity, diabetes, history of pre-eclamptic toxaemia and increasing age. After the age of thirty-five years, the patient and physician should carefully re-assess the risk/benefit ratio of using oral contraceptives as opposed to alternative methods of contraception.

- There is evidence that doses of progestogen higher than those used for contraception (5-30 mg daily vs 0.5 mg daily) may be associated with an increased risk of venous thromboembolism. Progestogens at doses used for contraception do not appear to be associated with an increase in risk of venous thromboembolism. Progestogen-only contraceptive pills may be considered as an option for contraception in women who have experienced DVT or PE with a combined oral contraceptive, provided the thromboembolic process has resolved. In most cases a progestogen-only contraceptive pill need not be discontinued for major surgery whether it does or does not involve immobilisation. In situations where there is a high risk of thrombosis, consideration should be given to discontinuation of Noriday.

Reasons for stopping oral contraception immediately:

- First signs of thrombophlebitis or thromboembolism, jaundice or pregnancy.
- A decrease in glucose tolerance has been observed in a significant percentage of patients on oestrogen-progestogen therapy. The mechanism of this decrease is obscure. For this reason diabetic patients as well as all other patients on NORIDAY 28 DAY therapy should be carefully observed for any of the previously mentioned occurrences.
- Hypertension, which is usually reversible on discontinuing treatment, has occurred in a small percentage of women taking oral contraceptives. Malignant hypertension has been associated with oral contraceptive use.
- NORIDAY 28 DAY should be used with caution in patients with a history of hepatic dysfunction.
- Any possible influence of prolonged NORIDAY 28 DAY therapy on pituitary, ovarian, adrenal, hepatic or uterine function awaits further study. The age of patient constitutes no absolute limiting factor, although treatment with NORIDAY 28 DAY may mask the onset of the climacteric.
- Progestogens may cause some degree of fluid retention. Conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.
- Visual disturbances have been associated with oral contraceptive use.
- Patients with a history of depression should be carefully observed and the medication discontinued if serious depression recurs.
- A usual feature of all progestogen-only oral contraceptives is that they produce an initial irregularity of the bleeding pattern, but such irregularity tends to decrease with time. The patient should be informed before starting NORIDAY 28 DAY tablets that her menstrual pattern is likely to alter. Irregular bleeding is, from a medical point of view, no reason for discontinuation of therapy, as long as organic causes and pregnancy can be ruled out. The patient should be advised that if prolonged bleeding occurs, she should consult her physician. The patient should be instructed that if two or more consecutive periods are missed, she should consult her physician in order to rule out pregnancy.
- Benign and malignant liver tumours have been associated with oral contraceptive use. The relationship between occurrence of liver tumours and use of female sex hormones is not known at present. These tumours may rupture causing intra-abdominal bleeding. If the patient presents with a mass or tenderness in the right upper quadrant or an acute abdomen, the possible presence of a tumour should be considered.
- An increased risk of congenital abnormalities, including heart defects and limb defects, has been reported following the use of sex hormones, including oral contraceptives, in pregnancy.
• It is advisable to discontinue the use of oral contraceptives three months before a planned pregnancy.
• Although after delivery or abortion it is customary to start oral contraception at the end of the first biphasic menstrual cycle, NORIDAY 28 DAY tablets may be started as early as the seventh day post-partum. Additional contraceptive measures should be employed for the first 14 days of tablet-taking.
• Small amounts of steroid materials appear in the milk. WHO studies suggest that progestogen-only contraceptives have no effect on lactation and the nursing child.
• Progestogen-only oral contraceptives such as NORIDAY 28 DAY may offer less protection against ectopic pregnancy than against intra-uterine pregnancy.
• Recovery of fertility may be delayed following oral contraceptive use.
• Pre-existing uterine fibroids may increase in size.
• The pathologist should be advised of NORIDAY 28 DAY therapy when relevant specimens are submitted. For further information see the section entitled “Interactions”.

Missed periods

• If the patient does not adhere to the prescribed schedule, the possibility of pregnancy should be considered at the time of the first missed period and further use of oral contraceptives should be withheld until pregnancy has been ruled out. It is recommended that for any patient who has missed two consecutive periods, pregnancy should be ruled out before continuing the contraceptive regimen. If pregnancy is confirmed the patient should be apprised of the potential risks to the foetus and the advisability of continuing the pregnancy should be discussed in the light of these risks.

Circumstances requiring additional contraceptive precautions other than the temperature, rhythm and cervical-mucus methods.

• When changing to NORIDAY 28 DAY tablets from other hormonal contraceptives, additional non-hormonal contraceptive measures should be employed until 14 consecutive tablets have been taken regularly.
• Vomiting or diarrhoea may reduce the effectiveness of the tablets by preventing them from being fully absorbed. In the case of repeated vomiting or continued diarrhoea, additional non-hormonal contraceptive measures should be employed for the remainder of that course.
• Interaction with other medicines. Some medicines accelerate the metabolism of oral contraceptives taken concurrently. Medicines suspected of having the capacity to reduce the efficacy of oral contraceptives are listed under the heading INTERACTIONS. It is advisable to use non-hormonal methods of contraception during treatment with such medicines.

ADVERSE EFFECTS

The following adverse effects have been observed in women taking progestogens:

breakthrough bleeding; spotting; change in menstrual flow; amenorrhoea; oedema; change in weight (increase or decrease); change in cervical erosions and cervical secretions; cholestatic jaundice; rash (allergic) with or without pruritus; melasma or chloasma; mental depression; gastrointestinal disturbance; breast changes (tenderness, enlargement and secretion); masculinisation of the female foetus; hirsutism.
INTERACTIONS

The interactions listed in this section have been associated with the use of oral contraceptives containing oestrogen and progestogen:

- Oral contraceptives may be rendered less effective by virtue of interaction with ampicillin, analgesics, antihistamines, antimigraine preparations, barbiturates, chloramphenicol, griseofulvin, isoniazid, neomycin, nitrofurantoin, penicillin V, phenytoin, primidone, rifampicin, sulphonamides, tetracycline and tranquillizers.

- Oral contraceptives may alter the effectiveness of other types of medicines, such as anticonvulsants, antihypertensive agents (for example, guanethidine), beta-blockers, hypnotics, hypoglycaemic agents, oral anticoagulants, theophylline, tranquillizers, tricyclic antidepressants and vitamins.

Progestogen contraceptives may cause alterations in certain laboratory estimations. These parameters may take two months to return to normal following discontinuation of oral contraceptive therapy.

With the following tests abnormal results may reflect a biological interference with the test itself and not an impairment of organ function:

- Increase in serum aminoacid levels
- Decrease in pregnanediol excretion.

With the following tests abnormal results may indicate impairment of organ function:

- Liver - increase in bilirubin, alkaline phosphatase and gamma glutamyl transpeptidase.

OVERDOSAGE

Symptoms:

Overdosage may be manifested by nausea, vomiting, breast enlargement and vaginal bleeding.

Treatment:

There is no specific antidote and treatment should be symptomatic.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C.

MEDICINE CLASSIFICATION

Prescription medicine.
PACKAGING QUANTITIES

Noriday 28 Day Calendar packs: 3 x 28.

FURTHER INFORMATION

Nil.

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