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# Use of the Cu-7 Device In a Family Planning Clinic

## SUMMARY

The experience of 707 women undergoing a first insertion of the Cu-7® at the Family Planning Clinic, Edmundston, has been assessed.

The majority (67.3%) of patients were parous, and 77.2% were 20-29 years of age. Insertion of the Cu-7 was considered easy in both nulliparous and parous patients.

Two years of use have been completed by 136 women (7,917 woman months of use).

Relevant life-table discontinuation rates for the first two years of use, respectively, were: involuntary pregnancy 1.50%, 1.39%; expulsion 6.60%, 1.11%; removal of the Cu-7 for some medical reason 19.83%, 14.85%.

Removals for pain among nulliparous women were significantly more frequent than among parous patients ( $p < .001$ ). (Can Fam Physician 1980; 26:1507-1514).

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a first insertion was performed prior to April 1, 1978.

## Method

Patients wishing to use an intra-uterine contraceptive device (IUD), or those in whom the physician considered this method desirable, were fitted with a Cu-7 after undergoing a thorough physical examination. Insertions

were usually performed during menses.

Patients returned approximately two months post-insertion for a follow-up examination; any complaints were noted. Thereafter, annual checkups were performed unless problems were encountered. The clinic nurse provided support and encouragement at all times, and patients were able to contact the clinic concerning any con-

**S**INCE ITS INTRODUCTION in 1974, the Cu-7 IUD has been routinely used at the Family Planning Clinic, Hôtel-Dieu Hospital, Edmundston. This clinic serves a community of approximately 13,000, predominantly French-Canadians. The staff consists of one physician and two nurses. In order to monitor the success of this device and any possible adverse effects, careful records were kept of all patients in whom a Cu-7 was inserted. To date, over 800 Cu-7 insertions have been performed. This report details the experience of the 707 women in whom

**TABLE 1**  
**Age and Parity Distribution of Study Population**

| Age                    | Parity      |             |            |            |            | Total        | % of Population |
|------------------------|-------------|-------------|------------|------------|------------|--------------|-----------------|
|                        | 0           | 1-2         | 3-4        | 5-6        | 7-9        |              |                 |
| 15-19                  | 64          | 27          | —          | —          | —          | 91           | 12.9            |
| 20-29                  | 165         | 340         | 39         | 1          | 1          | 546          | 77.2            |
| 30-39                  | 2           | 37          | 17         | 3          | 1          | 60           | 8.5             |
| 40-52                  | —           | —           | 2          | 4          | 3          | 9            | 1.3             |
| Not indicated          | —           | 1           | —          | —          | —          | 1            | 0.1             |
| <b>Total</b>           | <b>231</b>  | <b>405</b>  | <b>58</b>  | <b>8</b>   | <b>5</b>   | <b>707</b>   |                 |
| <b>% of Population</b> | <b>32.7</b> | <b>57.3</b> | <b>8.2</b> | <b>1.1</b> | <b>0.7</b> | <b>100.0</b> |                 |

cerns or complaints while wearing the device.

Initially, devices were removed routinely after two years of use. However, on insertion of a replacement device, patients sometimes encountered problems of pain and bleeding. Thus, a decision was made to forego routine removals of the Cu-7 after two years of use. Some patients have successfully worn the Cu-7 for three years of uninterrupted use.

## Data Analysis

The present report covers insertions during the period August 1, 1974 to April 1, 1978. Multiple decrement life-table analysis of the first two years of use was performed. First segment experience only has been considered. Although 25 women have successfully completed three years of uninterrupted use, these numbers are too small for life-table methods. Termination rates between nulliparous and parous patients were compared using the log-rank test, based on chi-square, described by Azen *et al.*<sup>1</sup>

**TABLE 2**  
**Contraceptive Method Employed Prior to Insertion of Cu-7**

| Method                           | Patients   |              |
|----------------------------------|------------|--------------|
|                                  | #          | %            |
| None                             | 86         | 12.2         |
| Oral contraceptives              | 415        | 58.7         |
| Intrauterine device              | 12         | 1.7          |
| Diaphragm                        | 1          | 0.1          |
| Condom                           | 43         | 6.1          |
| Foam/Jelly/Vaginal Suppositories | 7          | 1.0          |
| Rhythm                           | 32         | 4.5          |
| Withdrawal                       | 13         | 1.8          |
| Recent pregnancy                 | 9          | 1.3          |
|                                  | <b>618</b> | <b>87.4</b>  |
| Not indicated                    | 89         | 12.6         |
|                                  | <b>707</b> | <b>100.0</b> |

## Results

During the period between August 1, 1974 and April 1, 1978, 749 Cu-7 insertions were performed, of which 42 were reinsertions in previous users.

Thus, 707 patients had a first insertion. Table 1 details the age and parity distribution of the study population. The majority (67.3%) of patients were parous, and 77.2% were aged 20-29. More than half (58.7%) of the patients had been using oral contraceptives prior to insertion of the Cu-7 and a further 12.2% had used no form of contraception. Only 12 patients (1.7%) had been wearing an intrauterine device (Table 2).

Insertion of the Cu-7 posed no problems in either nulliparous or parous patients. No sedatives or local anesthetics were employed at the time of insertion. Approximately one in 22 (4.4%) insertions in parous women were associated with some pain, while approximately one in six (17.3%) nulliparous complained of some pain.

At the two month follow-up visit (Table 3), approximately half of the patients seen reported abdominal

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A feature of the College's 1981 Annual Scientific Assembly, to be held in historic Québec City, will be the presentation of freestanding papers on a variety of topics. Readers are invited to submit abstracts of proposed papers, which will be judged by the Scientific Program Committee for possible presentation.

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# Sinemet\*

## ANTIPARKINSON AGENT

Common adverse reactions that can occur with SINEMET\* are abnormal involuntary movements and, less frequently, mental changes. These usually can be diminished by dosage reduction.

### INDICATIONS

Treatment of Parkinson's syndrome with exception of drug induced parkinsonism.

### CONTRAINDICATIONS

When a sympathomimetic amine is contraindicated; with monoamine oxidase inhibitors, which should be discontinued two weeks prior to starting SINEMET\*; in uncompensated cardiovascular, endocrine, hematologic, hepatic, pulmonary or renal disease; in narrow-angle glaucoma; in patients with suspicious, undiagnosed skin lesions or a history of melanoma.

### WARNINGS

When given to patients receiving levodopa alone, discontinue levodopa at least 12 hours before initiating SINEMET\* at a dosage that provides approximately 20% of previous levodopa.

Not recommended in drug-induced extrapyramidal reactions; contraindicated in management of intention tremor and Huntington's chorea.

Levodopa related central effects such as involuntary movements may occur at lower dosages and sooner, and the 'on and off' phenomenon may appear earlier with combination therapy.

Monitor carefully all patients for the development of mental changes, depression with suicidal tendencies, or other serious antisocial behaviour.

Cardiac function should be monitored continuously during period of initial dosage adjustment in patients with arrhythmias.

Upper gastrointestinal hemorrhage is possible in patients with history of peptic ulcer.

Safety of SINEMET\* in patients under 18 years of age not established.

**Pregnancy and lactation:** In women of child-bearing potential, weigh benefits against risks. Should not be given to nursing mothers. Effects on human pregnancy and lactation unknown.

### PRECAUTIONS

**General:** Periodic evaluations of hepatic, hematopoietic, cardiovascular and renal function recommended in extended therapy. Treat patients with history of convulsions cautiously. **Physical Activity:** Advise patients improved on SINEMET\* to increase physical activities gradually, with caution consistent with other medical considerations. **In Glaucoma:** May be given cautiously to patients with wide angle glaucoma, provided intraocular pressure is well controlled and can be carefully monitored during therapy. **With Antihypertensive Therapy:** As symptomatic postural hypotension has been reported occasionally, give cautiously to patients on antihypertensive drugs, checking carefully for changes in pulse rate and blood pressure. Dosage adjustment of antihypertensive drug may be required. **With Psychoactive Drugs:** If concomitant administration is necessary, administer psychoactive drugs with great caution and observe patients for unusual adverse reactions. **With Anesthetics:** Discontinue SINEMET\* the night before general anesthesia and reinstitute as soon as patient can take medication orally.

### ADVERSE REACTIONS

**Most Common:** Abnormal Involuntary Movements—usually diminished by dosage reduction—choreaiform, dystonic and other involuntary movements. Muscle twitching and blepharospasm may be early signs of excessive dosage.

**Other Serious Reactions:** Oscillations in performance: diurnal variations, independent oscillations in akinesia with stereotyped dyskinesias, sudden akinetic crises related to dyskinesias, akinesia paradoxa (hypotonic freezing) and 'on and off' phenomenon. Psychiatric: paranoid ideation, psychotic episodes, depression with or without development

of suicidal tendencies and dementia. Levodopa may produce hypomania when given regularly to bipolar depressed patients. Rarely convulsions (causal relationship not established). Cardiac irregularities and/or palpitations, orthostatic hypotensive episodes, anorexia, nausea, vomiting and dizziness.

### Other adverse reactions that may occur:

**Psychiatric:** Increased libido with serious antisocial behaviour, euphoria, lethargy, sedation, stimulation, fatigue and malaise, confusion, insomnia, nightmares, hallucinations and delusions, agitation and anxiety. **Neurologic:** ataxia, faintness, impairment of gait, headache, increased hand tremor, akinetic episodes, "akinesia paradoxa", increase in the frequency and duration of the oscillations in performance, torticollis, trismus, tightness of the mouth, lips or tongue, oculogyric crisis, weakness, numbness, bruxism, priapism. **Gastrointestinal:** constipation, diarrhea, epigastric and abdominal distress and pain, flatulence; eructation, hiccups, sialorrhea; difficulty in swallowing, bitter taste, dry mouth; duodenal ulcer; gastrointestinal bleeding; burning sensation of the tongue. **Cardiovascular:** arrhythmias, hypotension, non-specific ECG changes, flushing, phlebitis. **Hematologic:** hemolytic anemia, leukopenia, agranulocytosis. **Dermatologic:** sweating, edema, hair loss, pallor, rash, bad odor, dark sweat. **Musculoskeletal:** low back pain, muscle pain and twitching, musculoskeletal pain. **Respiratory:** feeling of pressure in the chest, cough, hoarseness, bizarre breathing pattern, postnasal drip. **Urogenital:** urinary frequency, retention, incontinence, hematuria, dark urine, nocturia, and one report of interstitial nephritis. **Special Senses:** blurred vision, diplopia, dilated pupils; activation of latent Horner's syndrome. **Miscellaneous:** hot flashes, weight gain or loss. Abnormalities in laboratory tests reported with levodopa alone, which may occur with SINEMET\*: Elevations of blood urea nitrogen, SGOT, SGPT, LDH, bilirubin, alkaline phosphatase or protein bound iodine. Occasional reduction in WBC, hemoglobin and hematocrit. Elevations of uric acid with colorimetric method. Positive Coombs tests reported both with SINEMET\* and with levodopa alone, but hemolytic anemia extremely rare.

### DOSAGE SUMMARY

*In order to reduce the incidence of adverse reactions and achieve maximal benefit, therapy with SINEMET\* must be individualized and drug administration continuously matched to the needs and tolerance of the patient. Combined therapy with SINEMET\* has a narrower therapeutic range than with levodopa alone because of its greater milligram potency. Therefore, titration and adjustment of dosage should be made in small steps and recommended dosage ranges not be exceeded. Appearance of involuntary movements should be regarded as a sign of levodopa toxicity and an indication of overdosage, requiring dose reduction. Treatment should, therefore, aim at maximal benefit without dyskinesia.*

### Therapy in Patients not receiving Levodopa:

Initially ½ tablet once or twice a day, increase by ½ tablet every three days if desirable. An optimum dose of 3 to 5 tablets a day divided into 4 to 6 doses.

### Therapy in Patients receiving Levodopa:

Discontinue levodopa for at least 12 hours, then give approximately 20% of the previous levodopa dose in 4 to 6 divided doses.

FOR COMPLETE PRESCRIBING INFORMATION, PARTICULARLY DETAILS OF DOSAGE AND ADMINISTRATION, PLEASE CONSULT PRODUCT MONOGRAPH WHICH IS AVAILABLE ON REQUEST.

### HOW SUPPLIED

Ca8804—Tablets SINEMET\* 250, dapple-blue, oval, biconvex, scored, compressed tablets coded MSD 654, each containing 25 mg of carbidopa and 250 mg of levodopa. Available in bottles of 100 and 500.

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cramps, and 28.4% considered their menses heavy. Intermenstrual spotting was present in 34.9% of women. Often, patients specified that these symptoms were present during the first one or two cycles only, and resolved with continuing use of the device. Twenty-six percent of patients reported a vaginal discharge.

**TABLE 3**  
**Observations at Two Months\*  
Post-Insertion of Cu-7**

Number of patients seen: 557

| Complaint                            | Total Reports |      |
|--------------------------------------|---------------|------|
|                                      | #             | %    |
| Abdominal cramps                     | 281           | 50.4 |
| Pain                                 |               |      |
| Leg                                  | 8             | 1.4  |
| Back                                 | 16            | 2.9  |
| Side                                 | 10            | 1.8  |
| Breast                               | 5             | 0.9  |
| Other                                | 65            | 11.7 |
| Menstrual flow                       |               |      |
| Heavy                                | 158           | 28.4 |
| Lightly increased                    | 226           | 40.6 |
| No change                            | 103           | 18.5 |
| Intermenstrual spotting              |               |      |
| Occasional                           | 124           | 22.3 |
| Frequent                             | 70            | 12.6 |
| Vaginal discharge                    | 145           | 26.0 |
| Difficulty in finding<br>Cu-7 string | 23            | 4.1  |
| Awareness of Cu-7 string:            |               |      |
| Partner                              | 13            | 2.3  |
| Patient                              | 14            | 2.5  |
| Headache                             | 6             | 1.1  |
| Dyspareunia                          | 12            | 2.2  |

\* Actual time of visit within six months of insertion

Table 4 details multiple decrement life-table rates for terminations in the total study population, for the first two years of use.

Nine involuntary pregnancies were reported during the first year of use, and four during the second year of use, giving a two-year cumulative rate of 2.24%. All involuntary pregnancies were followed up. In one case, the pregnancy was ectopic, and the Cu-7 was removed at salpingectomy; three patients elected to terminate the pregnancy. Nine patients continued the pregnancy and all delivered normal, healthy babies; seven by vaginal deliv-

ery, and two by cesarean section. In five cases, the device remained *in situ* throughout the pregnancy.

As expected, expulsions were more frequent during the first months after insertion. The expulsion rate at three months was 3.96%—compared to 6.60% for the entire first year of use, and 1.11% for the second year of use.

The majority of removals during the first year were for pain and/or bleeding (17.54%). The rate declined during the second year of use (11.49%). Removals for pain were more frequent, with rates of 9.30% and 7.06% for the first and second years of use.

Removals for 'other medical reason'

include 15 removals for suspected pelvic inflammatory disease, of which three were diagnosed as cases of salpingitis and two as cases of endometritis. If infections are considered separately, the annual rates were 1.61% and 1.87% for the first two years, respectively, with a two-year cumulative rate of 2.61%.

One uterine perforation was reported which was detected during laparotomy for an ovarian cyst. One patient requested removal of the Cu-7 because of dyspareunia.

During the study, 80 patients had the device removed in order to become pregnant. Follow-up information was

available on 71 of these women, eight of whom later changed their mind and no longer desired pregnancy. Half of the women had conceived within three months of removal of the device, and 74.2% were pregnant within one year of removal. Of the 55 women who became pregnant, 40 delivered normal, healthy infants; seven miscarried within four months of conception; one baby was stillborn at full term; one premature infant died, and one infant had a congenital cardiac condition. The outcome of the pregnancy in five cases is not known.

Termination rates for nulliparous and parous patients are presented in Table 5. Only the first year of use has been considered, since an insufficient number of patients in each group have completed two years of use to permit a meaningful life-table analysis. Rates of involuntary pregnancy, expulsion and removals for medical reasons other than pain were very similar in the two groups. However, removals for pain among nulliparous women were significantly more frequent than among parous patients ( $p < 0.001$ ).

## Discussion

Patient experience with an IUD varies from one clinic to another, since not only is accurate placement of the device important, but supportive counselling influences patient attitude and acceptance of the device.<sup>2</sup>

The advent of smaller, efficacious IUDs, coupled with adverse publicity about the use of oral contraceptives, appears, at least in our experience, to have resulted in more women accepting intrauterine contraception. This is borne out in that only 1.7% of all patients requesting Cu-7 insertion had previously employed an IUD, while 58.7% had used oral contraceptives. Since 89.7% of Cu-7 acceptors were under 30, there seems to be a growing interest in intrauterine contraception among younger women in our patient population.

Rates for involuntary pregnancy during the first and second year of use were virtually identical (1.50%; 1.39%), and the two-year cumulative pregnancy rate of 2.24% compares with the 2.7% reported by Stewart *et al.*,<sup>3</sup> based on 16,402 insertions. Although insufficient numbers of patients have completed a third year of

**TABLE 4**  
Termination Rates (Multiple Decrement Life-Table) During The First Two Years of Cu-7 Use, In The Total Study Population

| Reason For Termination     | Year-Specific % Termination Rates |                | % Cumulative Rate 24 Months |
|----------------------------|-----------------------------------|----------------|-----------------------------|
|                            | 1st Year                          | 2nd Year       |                             |
| Involuntary pregnancy      | 1.50                              | 1.39           | 2.24                        |
| Expulsion                  | 6.60                              | 1.11           | 7.19                        |
| Removal For:               |                                   |                |                             |
| Pain                       | 9.30                              | 7.06           | 13.05                       |
| Bleeding                   | 6.29                              | 3.71           | 8.26                        |
| Both pain and bleeding     | 1.95                              | 0.72           | 2.33                        |
| Other medical reason       | 2.29                              | 3.36           | 4.08                        |
| Voluntary pregnancy        | 6.09                              | 16.14          | 14.67                       |
| Other non-medical reason   | 2.65                              | 5.10           | 5.36                        |
| All terminations           | 36.67                             | 38.59          | 57.18                       |
| Lost to follow-up          | 10.18                             | 9.03           | 14.98                       |
| <b>Woman months of use</b> | <b>5,425.5</b>                    | <b>2,491.5</b> | <b>7,917.0</b>              |

**TABLE 5**  
Termination Rates (Multiple Decrement Life-Table) In Nulliparous and Parous Women, During The First Year of Cu-7 Use

| Reason For Termination     | Nulliparae   | Parae        |
|----------------------------|--------------|--------------|
| Involuntary pregnancy      | 1.62         | 1.44         |
| Expulsion                  | 6.72         | 6.56         |
| Removal for:               |              |              |
| Pain                       | 17.30        | 5.98         |
| Bleeding                   | 7.89         | 5.31         |
| Both pain and bleeding     | 2.61         | 1.67         |
| Other medical reason       | 2.64         | 2.15         |
| Voluntary pregnancy        | 8.09         | 5.21         |
| Other non-medical reason   | 0.52         | 3.62         |
| All terminations           | 47.39        | 31.94        |
| Lost to follow-up          | 11.00        | 9.91         |
| <b>Woman months of use</b> | <b>1,539</b> | <b>3,870</b> |

use to permit statistical analysis, our impression, like several reports in the literature,<sup>3-5</sup> is that satisfactory contraceptive protection may be afforded beyond two years of use.

As has been noted by others,<sup>6</sup> the expulsion rate declined with time. The majority of expulsions occurred during the first three months post insertion and became very infrequent thereafter. This is reflected in the expulsion rate of 1.11% during the second year of use. Although for purposes of this analysis, a first expulsion was considered a closure, more than half of these patients requested a re-insertion of the device; three of the 23 re-insertions resulted in a second expulsion. All insertions were performed by one physician; of the first 100 insertions, 12 devices were eventually expelled; of the second 100 devices inserted, six

resulted in expulsion; of the third 100 devices inserted, six devices were expelled. All of these insertions were performed before the cut-off date for inclusion in this analysis so that length of time in the study is not a factor. Therefore, these data support a physician "learning effect" in the technique of correct placement of the device, which subsequently affects the patient's experience with the device.<sup>2</sup>

The majority of removals were related to pain and/or bleeding. Although removal rates for this reason reported in the literature show considerable variation,<sup>7</sup> the rate reported here (17.54%) is somewhat high. The rate of removal for pain among nulliparous women (17.30%) was significantly higher than that in parous women (5.98%), although termination rates for all other reasons, including

removal for bleeding, were very similar. Distortion of the uterine cavity by the plastic vector, rather than any property of copper, is thought responsible for cramping symptoms.<sup>7, 8</sup> The Cu-7 has a small horizontal dimension (28 mm); however, fundal width in normal women has been estimated to be 21-50 mm.<sup>9</sup> Thus, there will be women whose uterine cavity is simply too small to accommodate the IUD properly. Since nulliparae tend to have smaller uterine dimensions than parous women,<sup>11</sup> they could experience pain more frequently.

The Cu-7 did not appear to interfere with fecundity subsequent to removal of the device. Within 12 months after removal of the device for a planned pregnancy, 74.0% of patients had conceived. These data agree well with Southam's<sup>11</sup> estimate of a 73% suc-

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cess rate during the first year of attempted conception in the general population.

The Cu-7 has met with a high degree of acceptance among our patient population, and seems a particularly suitable contraceptive method for couples who wish to plan their family. ●

## Acknowledgement

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**Indication:** Conception control.

**Contraindications:** Thrombophlebitis, thromboembolic disorders, cerebral vascular disease, coronary thrombosis, or a history of these conditions; significant liver dysfunction or disease; history of cholestatic jaundice; known or suspected estrogen-dependent neoplasia; undiagnosed abnormal vaginal bleeding; known or suspected pregnancy; during the period a mother is breast-feeding an infant; any ocular lesion associated with ophthalmic vascular disease such as partial or complete loss of vision, defect in visual fields or diplopia; classical migraine.

**Warnings:** Discontinue medication at the earliest manifestations of: a) Thromboembolic disorders. b) Visual disturbances including: (i) gradual or sudden, partial or complete loss of vision; (ii) proptosis or diplopia; (iii) onset or aggravation of migraine; (iv) papilledema; (v) ophthalmic vascular lesions. (c) Development of headache which is recurrent, persistent or severe and undiagnosed. (d) Psychiatric disturbances. Rule out pregnancy in patients who have missed a menstrual period. Patients with epilepsy, diabetes mellitus, asthma and cardiac or renal dysfunction require careful observation. In women with predisposing factors for cardiovascular disease, oral contraceptives have been reported as an additional risk. After the age of 40 years, for purposes of fertility control, oral contraceptives should be considered only in exceptional circumstances, and when the risk/benefit ratio has been carefully weighed by both the physician and the patient.

**Precautions:** Before use, take a thorough history, and perform a thorough physical examination including a blood pressure determination and examination of breasts, liver and pelvic organs. A Pap Smear should be taken. First follow-up examination is at 6 months, and at least yearly thereafter, including all tests initially performed. Women with a history of jaundice should be prescribed oral contraceptives under close observation. If there is a history of cholestatic jaundice, especially during pregnancy, other methods of contraception should be prescribed. The development of severe generalized pruritis or icterus requires that the medication be withdrawn until the problem is resolved. If jaundice is cholestatic in type, do not resume oral contraceptive administration. Changes in composition of bile and the appearance of cholesterol gallstones have been reported in women taking oral contraceptives. Hepatic neoplasms and nodular hyperplasias or hamartomas have been reported in oral contraceptive users. Although these tumors are uncommon, they have caused fatal intra-abdominal hemorrhage and should be considered in women presenting with acute abdominal pain, an abdominal mass or evidence of intra-abdominal bleeding. Patients with essential hypertension may be prescribed oral contraceptives under close supervision. If a significant blood pressure elevation in previously normotensive or hypertensive subjects occurs at any time, cessation of medication is indicated. Diabetic patients or those with a family history of diabetes should be observed closely. Latent diabetics who can be kept under close supervision may be prescribed oral contraceptives. Young patients with overt diabetes whose disease is of recent origin, well-controlled and not associated with hypertension or other signs of vascular disease should be closely observed. In metabolic or endocrine diseases and when calcium and phosphorus metabolism is abnormal, careful clinical evaluation should precede medication. The risk of complications due to adrenocortical insufficiency appears to be minimal with oral contraceptive therapy. Estrogen-progestogen combinations may cause an increase in plasma lipoproteins and should be administered with caution to women known to have preexistent hyperlipoproteinemia. Use special judgement in prescribing oral contraceptives to women with fibrocystic breast disease. Persistent irregular vaginal bleeding requires investigation to exclude the possibility of pregnancy or neoplasm. Observe patients with fibroids carefully. Sudden enlargement, pain or tenderness of uterine fibroids require discontinuation of medication. Assess adolescent patients for adequate skeletal development prior to medication, since oral contraceptives may accelerate epiphyseal closure. Oral contraceptive therapy may mask the onset of the climacteric. In general,

women in the later reproductive years gradually assume an increasing risk of circulatory and metabolic complications, especially at age 35 to 40. Shorter duration of oral contraceptive use, and avoidance of cigarette smoking is advisable. Patients with a history of emotional disturbances, especially the depressive type, are more prone to have a recurrence. In cases of serious recurrence, the medication should be discontinued in favour of a non-hormonal method of contraception for a trial period to determine if the symptom is therapy related. The following laboratory tests should not be considered reliable unless oral contraceptive therapy has been discontinued for 2 to 4 months: liver function tests; coagulation tests; thyroid function tests; adrenocortical function tests; reproductive endocrine profile changes; and other tests involving phospholipids, triglycerides, serum folate, tryptophan metabolism, and serum glucose. Advise pathologists of oral contraceptive therapy when specimens are submitted for examination. After discontinuing oral contraceptives, the patient should use an alternate non-hormonal method of conception control and await the resumption of normal ovulatory cycles before attempting to become pregnant. Women with a history of oligomenorrhea or secondary amenorrhea or women with irregular cycles may remain anovulatory or become amenorrheic following estrogen-progestogen combination therapy. Fetal abnormalities have occurred in the offspring of women who have taken progestogens and/or estrogens during pregnancy. The safety of oral contraceptives in pregnancy has not been demonstrated. Rule out pregnancy before initiating or continuing the contraceptive regimen. Always consider pregnancy if withdrawal bleeding does not occur. Retrospective studies have reported an increased risk of post-surgery thromboembolic complications in oral contraceptive users. Therapy should be discontinued at least 1 month prior to elective surgery and not resumed until at least 2 weeks after hospital discharge following surgery associated with an increased risk of thromboembolism. A reduced efficacy and increased incidence of breakthrough bleeding have been reported in oral contraceptive users treated concomitantly with barbiturates, rifampicin, phenylbutazone, phenytoin or ampicillin. Protracted vomiting and/or diarrhea may decrease the absorption and effectiveness of oral contraceptives. Should these occur, an additional method of contraception should be recommended for the remainder of the cycle.

Adverse effects most commonly reported in early cycles of oral contraceptive therapy include breakthrough bleeding, spotting, nausea, vomiting and other gastrointestinal disturbances, weight change. These frequently decrease with continued use. Other common adverse effects are change in menstrual flow, edema, chloasma (which may persist post-therapy), amenorrhea, breast changes. In addition to the conditions and disorders discussed above, the following have been reported as adverse reactions: neurovascular lesions of the eye; rash; cervical erosion and secretions; suppression of lactation; premenstrual-like syndrome; changes in libido; leg cramps; relative pyridoxine deficiency; hemorrhagic eruptions; cholestatic jaundice; mental depression; migraine; cystitis-like syndrome; headache; nervousness; fatigue; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; itching; anovulation post-treatment; dizziness; thrombophlebitis; pulmonary embolism; hepatic neoplasm; cholesterol gallstones.

**Dosage:** ORTHO-NOVUM 1/35—21-day regimen: 1 tablet daily for 21 days followed by 7 days without medication. Cyclic administration.

ORTHO-NOVUM 1/35—28-day regimen: 1 tablet daily, 21 active tablets followed by 7 inert tablets. Continuous administration.

**Supplied:** Each tablet engraved on both sides with "Ortho 1" contains: norethindrone 1 mg and ethinyl estradiol 35 mcg. In the 28-day regimen the green tablets contain inert ingredients. Available in a 21-day or 28-day DIALPAK\* Tablet Dispenser.

**References:** 1. Pasquale, S. A., Morigi, E. M.: Recent Results of Clinical Studies on a Low-Dose Oral Contraceptive, Ortho Pharmaceutical Corporation, Raritan, New Jersey.

2. ORTHO-NOVUM 1/35 Product Monograph. Product Monograph available on request.

# ORTHO-NOVUM\* 1/35

1 MG NORETHINDRONE 35 MCG ETHINYL ESTRADIOL TABLETS

THE NAME SAYS IT ALL

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ORTHO PHARMACEUTICAL  
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Don Mills, Ontario

