PRODUCTS

Continuous Glucose Monitor

The Food and Drug Administration has approved a device that measures glucose for up to 7 days in people with diabetes. The STS-7 Continuous Glucose Monitoring System includes a subcutaneous, patientinsertable sensor that wirelessly transmits glucose readings to a handheld receiver, providing real-time measurements and trend information. Sensor placement causes minimal discomfort. The sensor must be replaced weekly. For more information, contact DexCom Inc., by calling 858-200-0200 or visiting www.dexcom.com.

Office Diagnostic Lab Analyzer

The Data Pro Plus is a compact, automated benchtop analyzer designed for routine diagnostic laboratory use in physician offices. It has a throughput of up to 230 tests per hour, onboard reagent management, and unlimited storage capacity for patient and control data. For more information, contact Thermo Scientific at 800-588-9115.

Coverlets for Breast-Feeding in Public

Bébé au Lait nursing coverlets are available for women who prefer to cover up when they breast-feed in public. The covers feature a patented rigid neckline that allows mother and child to see each other. They cost \$35, are made of European fabrics, and are available at upscale baby and maternity boutiques. For more information, visit www.bebeaulait.com.

Tissue Expander Helps Healing

The DermaClose RC Continuous External Tissue Expander facilitates the closure of large wounds by expanding the skin surrounding the wound until it can be sutured. The device has 10 skin anchors and a tension controller to prevent overtightening. In most cases, the wound can be sutured within 24 hours, which results in lowering both the costs and risks associated with wound healing. For more information or to order the product, visit www.woundcaretech.com.

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FYI

Public Diabetes Prevention Initiative

The American Diabetes Association (ADA) has launched CheckUpAmerica, which is aimed at people who are at risk of type 2 diabetes and heart disease. The initiative encourages people older than 40 years to have regular checkups and take steps to reduce their risk. The program includes a nationwide radio media tour by Dr. John Buse of the ADA. An online personal assessment tool will be available later this year. For more information, visit the ADA's Web site, www.CheckUpAmerica.org.

Quality Reporting Answers Online

More than 50 frequently asked questions about the Physician Quality Reporting Initiative are available on the Web site of the Centers for Medicare and Medicaid Services. Visit www.cms.hhs.gov/PQRI and scroll down to the "Related Links Inside CMS" section. Click on the "All PQRI FAQs" link to access the list.

FDA Guidance on Drug Safety

A new guidance document from the Food and Drug Administration, "Drug Safety Information—FDA's Communication to the Public" facilitates patient and provider access to information about a drug's risks and benefits. It supersedes the draft guidance "FDA's 'Drug Watch' for Emerging Drug Safety Information" and is available at www.fda.gov/cder/guidance/7477fnl.htm.

Doctor-Patient Partnering Guide

The American Medical Association and the American Association of Retired Persons have produced a free pamphlet that outlines shared responsibilities with a goal to improve patient safety by encouraging patients to be partners with physicians in managing their health. For more information, contact the AMA by visiting www.ama-assn.org/ama1/pub/up load/mm/370/amaaarpmessage.pdf.

SEASONIQUE™

(levonorgestrel / ethinyl estradiol tablets) 0.15 mg / 0.03 mg and (ethinyl estradiol tablets) 0.01 mg
Brief Summary, See full package brochure for complete information.
Patients should be counseled that this product does not protect against HIV-infection (AIDS) and other sexually transmitted diseases.
CONTRAINOICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: • Thrombophlebitis or throm-

boembolic disorders • A past history of deep vein thrombophlebitis or thromboembolic disorders • Cerebrovascular or coronary artery disease (current or history) • Valvular heart disease with thrombogenic complications • Uncontrolled hypertension • Diabetes with vascular involvement • Headaches with focal neurological symptoms • Major surgery with prologged immobilization • Known or suspected carcinoma of the breast or personal history of have the control of the endometrium or other known or suspected strogen dependent neoplasts a 'Undiagnosed abnormal genital biseding

Cholestatic jaundice of pregnancy or jaundice with prior pill use

Hepatic adenomas or carcinomas, or active liver disease

Known or suspected pregnancy • Hypersensitivity to any component of this product

VARIANTIUS. Cigarethe smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarethes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strong

Cligarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more disparettes) per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including venous and arterial thrombotic and thromboembolic nevents (such as myocardial infarction, thromboembolism, and stroie), hepatic neoplesis, pallbadder disease, and hypertension. The risk of seriodisy and motality increases significantly in the presence of other underlying risk factors such as certain inherited thrombophilias, hypertension, hypertension, between diseases, significantly in the presence of other underlying risk factors such as certain inherited thrombophilias, hypertension, hypertension, between diseases and oral diseases and prospective or additional process of process and prospective or additional representation or service of the process of the service of the research of increased risk of stoke. ** d. Dose-Picitied Risk of Viscolar Disease from Oral Contraceptives A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease. A define in serum Injury desirely Injury proteins (FIL) has been reported with many progestorial agents. A define in serum Injury desirely Injury proteins are serviced and association and and solution amount of progestogen used in the contraceptive. The amount of both homomes should be considered in the ordinaceptive. The amount of both homomes should be considered in the ordinaceptive. The amount of both homomes should be considered in the ordinaceptive. The amount of both homomes should be considered in the ordinaceptive great and the new properties of the properties. The amount of both homomes should be considered in the ordinaceptive great should be started on preparations containing the lowest extragen combination is judged appropriated should be one which contains the less amount of other goard progestogen contraceptives in judged appropriate for the individual patient. New acceptors of ordinaceptives are should be started on preparations containing the lowest extragen content, which is judged appropriate for the individual patient. New acceptors of risk of Viscoliate Rosace There are two stokes, which have shown presistence of risk of viscoliate disease for ever-users of oral contraceptives in a study in the United States, the risk of developing myocardial infarction after of the continuing oral contraceptive spersists for at least 9 years for women 40 to 49 years old who had used oral contraceptives for five or more years, but this increased risk was not demonstrated in other age groups. In another study in Great Brian, the risk of developing cerebrowascular disease experts and the study of the

Reference: 1. Data on file. Duramed Pharmaceuticals Inc, Pomona, NY.

findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogens and progestogens.

8. Carbohydrate and Lipid Metabolic Effects: Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Oral contraceptives containing greater than 75 micrograms of estrogens cause heigh lower doses of estrogen cause less glucose intolerance. Progestogens increase insulin secretion and create insulin resistance, this effect varying with different progestational agents. However, in the nondiable woman cal contraceptives appear to have no effect on fasting blood glucose. Because of these demonstrated effects, periabelite and diabelic women should be carefully observed while taking oral contraceptives. A small proportion of women will have persistent hypertriglyceridemia while on the pill. As discussed earlier (see WARNINGS 1a. and 1d.), changes in serum triglycerides and liopoporation diverse have been reported in oral contraceptive users.

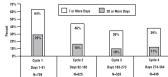
9. Elevated Blood Pressure: Women with Significant hypertension should not be started on hormonal contraceptive users.

9. Elevated Blood Pressure: Women with Significant hypertensions should be discontinued use. Data from the Royal College General Practitioners and subsequent andorimed trials have shown that the indicance of hypertension increases with increases inconcentrations of progestogens. Women with hypertension or hypertension-related diseases, or renal diseases should be encouraged to use another method of contraceptive should be discontinued (see CONTRAINIDCATIONIS). For most women, elevated blood pressure with return to normal after stopping oral contraceptives, and there is no difference in the cocurrence of hypertension among ever- and never-users.

10. Headdone: The most or exacethering of seasonique with continuation of oral contraceptives and evaluation of the cause. (See WARNINGS. 1c.)

11. Bleeding Irreputatives. When prescribiopants in the study (N=1.06) were compos

Figure: Percentage of Women Taking Seasonique™ Reporting Intermenstrual Bleeding and/or Spotting.



As in any case of bleeding irregularities, nonhormonal causes should always be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy. In the event of amenorthea, pregnancy should be ruled out. Some women may encounter post-pill amenorthea or oligomenorthea (possibly with annoutation), especially when such a condition was preexistent.

PREAUTIONS

1. Sexually Transmitted Diseases: Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

2. Physical Examination and Follow-up: A periodic history and physical examination are appropriate for all women, including women using oral contraceptives. The physical examination however, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including certical cytology, and relevant beloratory tests. In case of undiagnosed, presistent or recursed abnormal vaginal bleeding, appropriate diagnostic measures should be conducted to rule out nalignancy. Women with a strong paintly history of the rest cancer or who have breast notables should be monitored with particular care.

3. Lipid Disorders: Women with a strong paintly history of the peripidemies should be followed dosely if they elect to use oral contraceptives. Some progestogens may elected. Lib. Leves and may render the control of hyperipidemies more difficult. (See WARNINES of 14) in patients with finalial detects of lipoprotein metabolism receiving estrogen-containing preparations, there have been case reports of significant elevations of plasma triglycerides leading to pancreatitis.

4. Liver Function: It jaundice develops in any woman receiving such drugs, the medication should be discontinued. Steroid hormones may be poorly metabolized in patients with impaired liver function.

oils m receiving estrogen-containing preparations, there have been case reports of significant elevations of plasma triplycatell letteds.

4. Liver Function: If journalise develops in any woman receiving such drugs, the medication should be discontinued. Steroid hormones may be poorly metabolized in patients with impaired liver function.

5. Fluid Retention: Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions, which implied here aggravated by fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions, which might be aggravated by fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions, which might be aggravated by fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients.

6. Emotional Disorders: Women with a history of depression should be carefully observed and the drug discontinued if depression recurs to a serious degree. Patients becoming significantly depressed while taking oral contraceptives should stop the medication and use an alternate method of contraception in an attempt to determine whether the symptom is drug related.

7. Contact Lenses: Contact-lens wearrs who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

8. Drug Interactions: Changes in contraceptive effectiveness associated with no administration of other products. *a. Anti-infective agents and anticonvolusants. Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administration of other products. *a. Anti-infective agents and anticonvolusants. Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administration of contraceptive seriods. This could result in unintended pregnancy or breakthrough bleeding. Examples include finaling, in a contraceptive seriod of contracepti

contrations of adeamnopher and increased oberance of temazepam, saliopid and, morphine and clofibric acid, due to induction of conjugation have been noted when these drugs were administered with combination oral contraceptives.

9. Interactions with Laboratory tests - See Package Insert for complete information.

10. Carcinogenesis: See WARNINGS 11. Pregnancy: Pregnancy Category X See CONTRAINDICATIONS and WARNINGS 12. Nursing Mothers: Small amounts of oral contraceptives steroids and/or metabolites have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast entargenment. In addition, oral contraceptives given in the postpatrum period may interfere with lactation by decreasing the quantity and quality of breast milk. If possible, the nursing mother should be advised not to use oral contraceptives but to use other forms or contraceptive with she has completely weared the roll of 3. Pediatric lises: Seatest and efficacy of Seasonique** blacks have been established in women of reproductive age. Safety and efficacy are expected to be the same in postpubertal addissornts under the age of 16 and users 16 and older. Use of Seasonique** blacks have been established in women of reproductive age. Safety and efficacy or secondary are expected to be the same in postpubertal addissornts under the age of 16 and users 16 and older. Use of Seasonique** blacks have not been studied in women who have reached menopause.

NOVERSE RABACTIONS. In Introduction of the contraceptive seems and introduce of the same in postpubertal addissornts under the age of 16 and users 16 and older. Use of Seasonique** blacks have not been studied in women who have reached menopause.

NOVERSE RABACTIONS. In Introduction of the contraceptive season in Introduction of the same in the season of

OVERDOSAGE: Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may

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Duramed Pharmaceuticals, Inc. Subsidiary of Barr Pharmaceuticals, Inc. Pomona, New York 10970

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