LIDEX® (fluocinonide)
0.05% Cream and Ointment
TOPSYN™ (fluocinonide)
0.05% Gel

Summary of prescribing information

DESCRIPTION
LIDEX cream 0.05%, LIDEX ointment 0.05% and TOPSYN gel 0.05% contain the active compound fluocinonide. Fluocinonide, which is the 21-acetate ester of fluocinolone acetonide, has the chemical formula 6α, 9α, -difluoro-11β, 16α, 17α, 21-tetrahydroxypregna-1,4-diene-3, 20-dione, cyclic 16, 17-acetal with acetone 21-acetate.
LIDEX cream contains fluocinonide in FAPG® cream, a specially formulated cream base consisting of stearyl alcohol, polyethylene glycol 6000, propylene glycol, 1, 2, 6-hexanetriol and citric acid. This white cream vehicle is greaseless, non-staining, anhydrous and completely water miscible. The base provides emollient and hydrophilic properties. In this formulation, the active ingredient is totally in solution.
LIDEX ointment contains fluocinonide in a specially formulated ointment base consisting of Amerchol CAB (mixture of sterols and higher alcohols), white petrolatum, propylene carbonate and propylene glycol. It provides the occlusive and emollient effects desirable in an ointment. In this formulation the active ingredient is totally in solution.
TOPSYN gel contains fluocinonide in a specially formulated gel base consisting of propylene glycol, propyl gallate, disodium edetate, and Carbopol 940 (carboxypolymethylene) with NaOH and/or HCL added to adjust the pH. This clear, colorless, thixotropic vehicle is greaseless, non-staining and completely water miscible. In this formulation, the active ingredient is totally in solution.

INDICATIONS
LIDEX cream and ointment and TOPSYN gel are intended for the relief of inflammatory manifestations of corticosteroid responsive dermatoses.

CONTRAINDICATIONS
Topical steroids are contraindicated in vaccinia and varicella. Topical steroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS
If irritation develops, the cream, ointment or gel should be discontinued and appropriate therapy instituted. In the presence of an infection the use of an appropriate antifungal or antibacterial agent should be instituted.
If a favorable response does not occur promptly, the corticosteroid cream, ointment or gel should be discontinued until the infection has been adequately controlled.
If extensive areas are treated, the possibility exists of increased systemic absorption and suitable precautions should be taken.
Although topical steroids have not been reported to have an adverse effect on pregnancy, the safety of their use in pregnant females has not absolutely been established. Therefore, they should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time.
LIDEX® (fluocinonide) cream and ointment and TOPSYN® (fluocinonide) gel are not for ophthalmic use.

ADVERSE REACTIONS
The following local adverse reactions have been reported with topical corticosteroids:

burning	folliculitis
itching	acneform eruptions
irritation	hypopigmentation
dryness	striae
secondary infection	skin atrophy

DOSAGE AND ADMINISTRATION
A small amount should be gently massaged into the affected area three or four times daily, as needed.

HOW SUPPLIED
LIDEX 0.05% Cream—15 g 30 g and 60 g tubes.
LIDEX 0.05% Ointment—15 g 30 g and 60 g tubes.
TOPSYN Gel 0.05% 15 g and 60 g tubes.

SYNTEX
SYNTEX LABORATORIES, INC.
PALO ALTO, CALIFORNIA 94304

Migraine...and more

E Diazepam, 5 mg tid

EIGHT: The role of certain foods in the precipitation of migraine or migraine-like headaches in selected patients is well recognized. Which of the following statements is true?

A Diet and specific foods play some role in every patient with migraine headaches
B Aged cheeses may cause headaches because of the tyrosine content
C Cured meats and hot dogs should be avoided in selected migraine patients because of the sodium nitrite additive
D The patient needs a high-carbohydrate diet to avoid hypoglycemia
E Italian food should be avoided, as it's high in monosodium glutamate, a frequent offender

NINE: The use of analgesics for headache pain and the use of vasoconstrictors for treatment and prevention of the underlying pathophysiology is fraught with risks and complications. Which of the following drugs is not properly matched with a serious complication?

A Methysergide—retroperitoneal fibrosis with hydronephroses
B Oral isometheptene—termination of pregnancy
C Phenacetin—renal failure
D Ergotamine—peripheral vascular disease
E Aspirin—gastrointestinal bleeding

TEN: Toxic vascular headaches can result from many diverse factors, but cerebral vasodilatation is the common denominator. Which of the following won't cause this type of headache?

A Influenza
B Excessive alcohol intake
C Insulin overdose
D Hyperventilation (with low P_{CO_2})
E Vigorous exercise

DARVOCET-N® 100
propoxyphene napsylate with acetaminophen
Indication: For the relief of mild to moderate pain, either alone or accompanied by fever. **Contraindications:** Hypersensitivity to propoxyphene or to acetaminophen. **Warnings:** *Drug Dependence*—Propoxyphene can produce drug dependence characterized by psychic dependence and, less frequently, physical dependence and tolerance. Propoxyphene will only partially suppress the withdrawal syndrome in individuals physically dependent on morphine or other narcotics. The abuse liability of propoxyphene is qualitatively similar to that of codeine although quantitatively less, and propoxyphene should be prescribed with the same degree of caution appropriate to the use of codeine. *Usage in Ambulatory Patients*—Propoxyphene may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery. The patient should be cautioned accordingly. *Usage in Pregnancy*—Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, propoxyphene should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards. *Usage in Children*—Propoxyphene is not recommended for use in children, because documented clinical experience has been insufficient to establish safety and a suitable dosage regimen in the pediatric age group. **Precautions:** Confusion, anxiety, and tremors have been reported in a few patients receiving propoxyphene concomitantly with orphenadrine. The central-nervous-system depressant effect of propoxyphene may be additive with that of other C.N.S. depressants. **Adverse Reactions:** The most frequent adverse reactions are dizziness, sedation, nausea, and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include constipation, abdominal pain, skin rashes, lightheadedness, headache, weakness, euphoria, dysphoria, and minor visual disturbances. The chronic ingestion of propoxyphene in doses exceeding 800 mg. per day has caused toxic psychoses and convulsions. [011375]

DARVON® COMPOUND-65
propoxyphene hydrochloride, aspirin, phenacetin, and caffeine
Indication: For the relief of mild to moderate pain. **Contraindication:** Hypersensitivity to propoxyphene, aspirin, phenacetin, or caffeine. **Warnings:** *Drug Dependence*—Propoxyphene can produce drug dependence characterized by psychic dependence and, less frequently, physical dependence and tolerance. Propoxyphene will only partially suppress the withdrawal syndrome in individuals physically dependent on morphine or other narcotics. The abuse liability of propoxyphene is qualitatively similar to that of codeine although quantitatively less, and propoxyphene should be prescribed with the same degree of caution appropriate to the use of codeine. *Usage in Ambulatory Patients*—Propoxyphene may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery. The patient should be cautioned accordingly. *Usage in Pregnancy*—Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Therefore, propoxyphene should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards. *Usage in Children*—Propoxyphene is not recommended for use in children because documented clinical experience has been insufficient to establish safety and a suitable dosage regimen in the pediatric age group. Salicylates should be used with extreme caution in the presence of peptic ulcer or coagulation abnormalities. **Precautions:** Confusion, anxiety, and tremors have been reported in a few patients receiving propoxyphene concomitantly with orphenadrine. The central-nervous-system depressant effect of propoxyphene may be additive with that of other C.N.S. depressants. Phenacetin has been reported to damage the kidneys when taken in large amounts for a long time. Salicylates may enhance the effect of anticoagulants and inhibit the uricosuric effect of uricosuric agents. **Adverse Reactions:** The most frequent adverse reactions are dizziness, sedation, nausea, and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include constipation, abdominal pain, skin rashes, lightheadedness, headache, weakness, euphoria, dysphoria, and minor visual disturbances. The chronic ingestion of propoxyphene in doses exceeding 800 mg. per day has caused toxic psychoses and convulsions. [011375]

Lilly
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Additional information available to the profession on request.
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