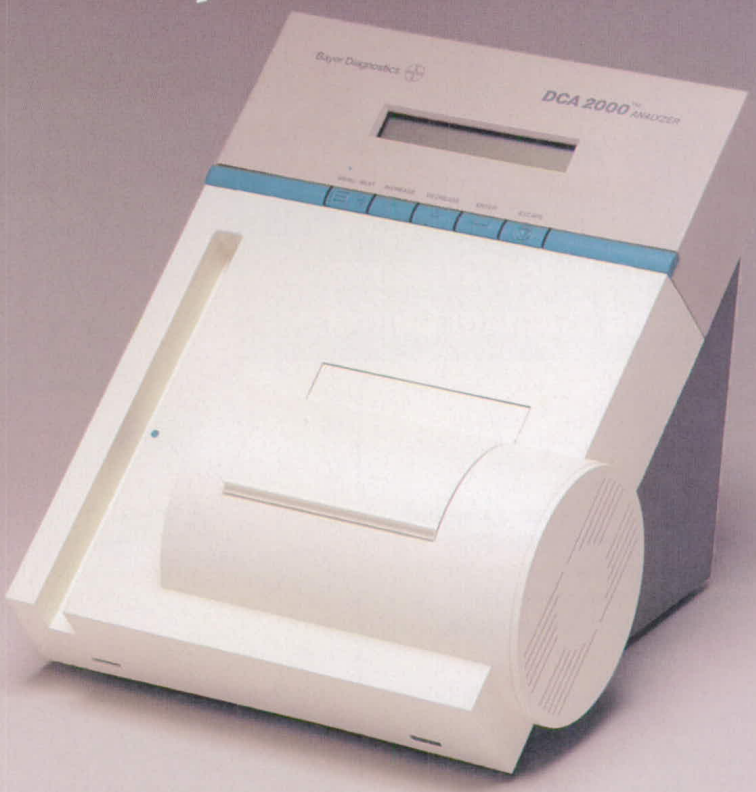
HbA1c
Improve control...
with the patient...in minutes



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The Diabetes Control and Complications Trial (DCCT) outcomes suggest that careful diabetes control, using frequent HbA_{1c} measurements, can significantly reduce the risk of complications.[1]

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1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329:977-986.

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Includes the content areas for meeting the standards of ADA Education Program Recognition

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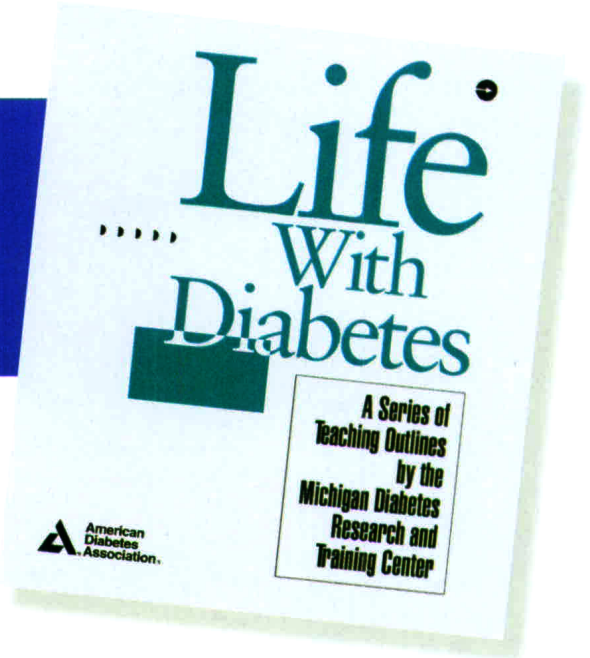
A Series of Teaching Outlines by the Michigan Diabetes Research and Training Center



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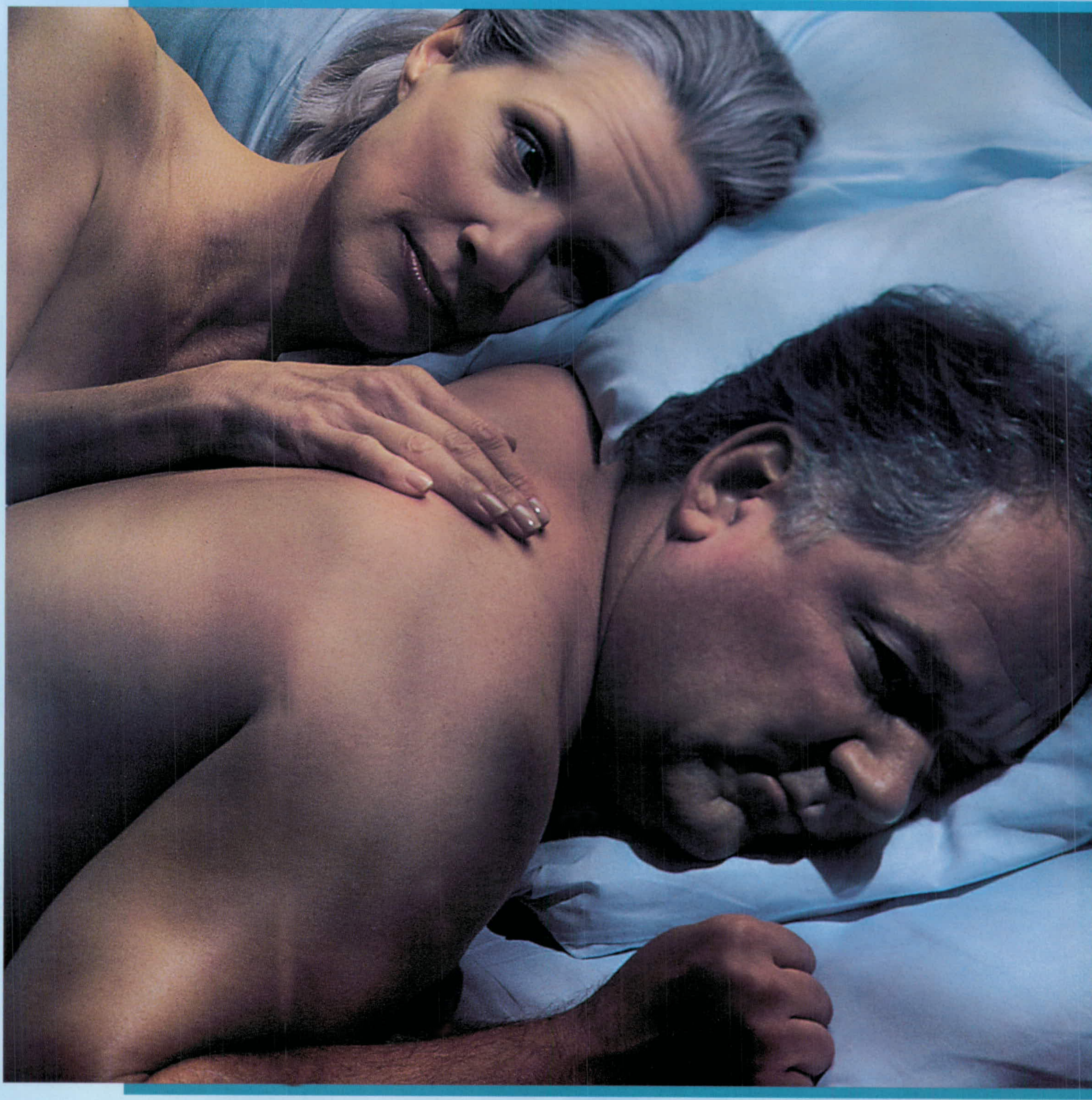
WHEN THE RELATIONSHIP SUFFERS FROM ERECTILE DYSFUNCTION



NOW THERE'S E D

The EDEX patient kit contains everything needed for self-injection:

- Single-dose vial of lyophilized powder
- Prefilled syringe with sterile diluent and plunger rod
- Two ½-inch needles: 27G and 30G
- Two alcohol swabs
- Detailed patient instructions

*EDEX is not a cure for erectile dysfunction. The underlying treatable medical causes should be diagnosed and treated prior to initiation of therapy. The therapeutic effect of each dose is temporary. If priapism occurs, the patient should seek immediate medical attention. EDEX should be used no more than 3 times per week with at least 24 hours between each dose.

EDEX is contraindicated in men with known hypersensitivity to alprostadil or other prostaglandins, men with conditions that might predispose them to priapism, and patients with penile implants or anatomical deformities of the penis. EDEX should not be used in men for whom sexual activity is inadvisable or contraindicated.

The injection of EDEX can induce a small amount of bleeding at the site of injection. Patients should be counseled about the protective measures that are necessary to guard against sexually transmitted or blood-borne diseases.

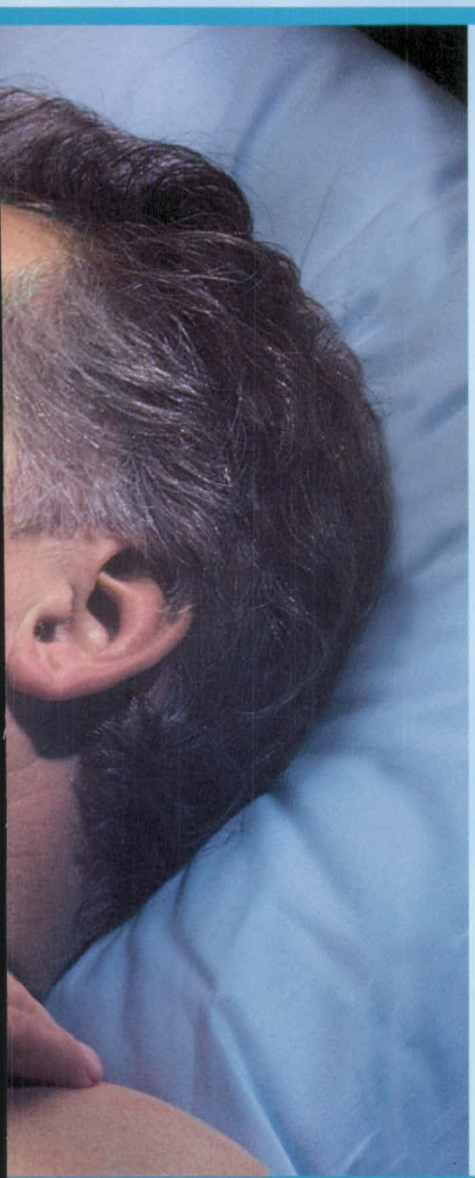
†588 of 894 patients had an optimum dose determined during the titration period. Patients received in-office evaluations, dose titration, and proper training techniques prior to the open-label, at-home extension period, which ranged from 6 to 12 months.

‡Based on direct cost per microgram for the at-home patient pack: EDEX, 5 mcg, $1.99; 10 mcg, $1.32; 20 mcg, $0.85; 40 mcg, $0.62. Caverject, 5 mcg, $2.17; 10 mcg, $1.45; 20 mcg, $0.93; 40 mcg, N/A. Price comparison does not imply comparable safety or efficacy. Prices may not reflect actual prices paid by patients or pharmacies.

Caverject® (alprostadil for injection) is a registered trademark of Pharmacia & Upjohn.

Please see brief summary of prescribing information.

E X™ (ALPROSTADIL FOR INJECTION)



Effectively restores erectile function...

Impressive at-home efficacy rates in clinical trials, 539 patients who self-injected EDEX at home had a mean rate of response, with an erection sufficient for intercourse, of 85% to 89%.[†1]

Confidently restores erectile function...

Established safety profile in clinical trials involving 1,065 patients with erectile dysfunction. The most common side effect experienced by patients was penile pain, reported by 31% of EDEX patients vs 9% of placebo patients in placebo-controlled studies. Patients judged the intensity of painful injections as mild (80%), moderate (16%), or severe (4%). Patient reports of penile pain decreased over time.

...with important benefits for you and your patients

Four dosage strengths (5, 10, 20, 40 mcg).
Simplifies the titration process and allows for economical dosing.

Priced lower than Caverject.®
Microgram per microgram, EDEX is less expensive than Caverject,® providing your patients an effective, yet more affordable treatment option.[‡1,2]

Refrigeration is not necessary.
Room temperature storage is convenient for both you and your patients.

Two injection choices.
Patients can choose a 27G or the thinner 30G sterile needle.

Complete patient support.
Comprehensive education and support for your patients with valuable tools for your office.

E D E X™

(ALPROSTADIL FOR INJECTION)

STERILE POWDER

RESTORE ERECTILE FUNCTION*

Detailed EDEX product information is available through your Schwarz Pharma representative and through our Internet web site: **www.edex.com**

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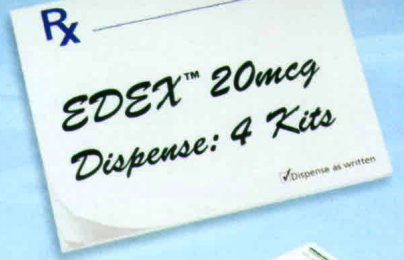
(ALPROSTADIL FOR INJECTION)

STERILE POWDER

RESTORE ERECTILE FUNCTION*



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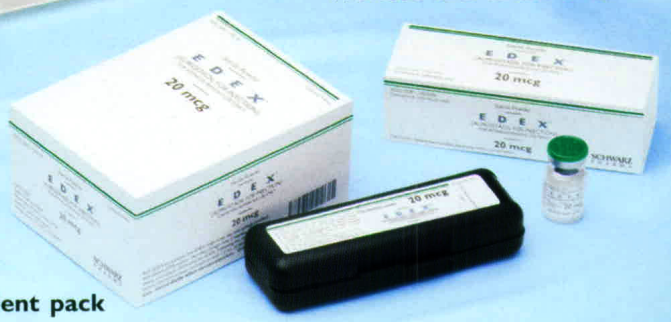
Provided in a carton of six



At-home patient pack
Everything needed for four self-injections

EDEX™

(alprostadil for injection)
For Intracavernous Use Only
Sterile Powder

The following is a Brief Summary. For complete prescribing information, see package insert.

INDICATIONS AND USAGE: Treatment of erectile dysfunction due to neurogenic, vasculogenic, psychogenic, or mixed etiology.

CONTRAINDICATIONS: Known hypersensitivity to alprostadil or other prostaglandins; conditions that might predispose the patient to priapism, such as sickle cell anemia or trait, multiple myeloma, or leukemia; anatomical penile deformity, such as angulation, cavernosal fibrosis, or Peyronie's disease; **and penile implants.** EDEX should not be used in men for whom sexual activity is inadvisable or contraindicated. Do not use EDEX in women, children, or newborns.

WARNINGS: Prolonged erections >4 hours occurred in 4% of patients treated up to 24 months. Incidence of priapism (erections >6 hours) was <1% with use for up to 24 months. In most cases, spontaneous detumescence occurred. Pharmacologic intervention and/or aspiration of blood from the corpora was necessary in 1.6% of 311 patients with prolonged erections/priapism. Titrate EDEX slowly to the lowest effective dose to minimize the chance of prolonged erection or priapism. Instruct the patient to immediately report and seek medical assistance for any erection that persists longer than 6 hours. Failure to treat priapism immediately may result in penile tissue damage and permanent loss of potency.

PRECAUTIONS: *General:* 1) EDEX can lead to increased peripheral blood levels of PGE_1 and its metabolites, especially in patients with significant corpora cavernosa venous leakage; hypotension and/or dizziness may occur. 2) Use regular patient follow-up, with careful examination of the penis at the start of therapy and at regular intervals (e.g. 3 months), to identify any penile changes. Penile fibrosis, including Peyronie's disease, was reported in 7.8% of patients in clinical studies up to 24 months. Stop treatment with EDEX in patients who develop penile angulation, cavernosal fibrosis, or Peyronie's disease. Treatment can be resumed if the penile abnormality subsides. 3) EDEX combined with other vasoactive agents was not systematically studied; the use of such combinations is not recommended. 4) After EDEX injection, compress the injection site for five minutes or until bleeding stops. Anticoagulant therapy, such as warfarin or heparin, may increase the tendency for bleeding after injection. 5) Diagnose and treat underlying treatable medical causes of erectile dysfunction before starting therapy with EDEX. 6) Instruct the patient not to re-use or share needles or syringes and not to let anyone else use his prescription medicines. 7) *Drug Interactions:* Exercise caution with concomitant administration of heparin and EDEX. *Information for Patients:* Thorough training in self-injection technique is required before EDEX can be used at home. The dose is established in the physician's office. Carefully follow preparation instructions included with EDEX. Discard vials with precipitates or discoloration. If dosage prescribed is <1 mL, the entire amount of solution will not need to be withdrawn to reach the prescribed dose. Properly discard needles after use; do not re-use or share with others. Use solution immediately after reconstitution. Follow the instructions in the patient information pamphlet. The vial is designed for single use; therefore, discard the vial and any remaining solution once the proper amount is withdrawn. Do not change the prescribed dose without physician consultation. EDEX should produce an erection in 5 to 20 minutes. Do not exceed an injection frequency of 3 times per week; separate each use by at least 24 hours. Patients should know the possible side effects of EDEX and what to do if side effects occur. Patients must return for regular checkups for treatment benefit and safety assessments. Counsel patients about protective measures necessary to guard against the spread of sexually transmitted diseases, including the human immunodeficiency virus (HIV). The small amount of injection-site bleeding that can occur in some patients could increase the risk of transmitting blood-borne diseases between partners. *Carcinogenesis, Mutagenesis, Impairment of Fertility:* Long-term carcinogenicity studies have not been conducted. Alprostadil was not mutagenic in a variety of assays. Alprostadil did not cause any adverse effects on fertility or general reproductive performance when administered intraperitoneally to male or female rats. *Pregnancy, Nursing Mothers and Pediatric Use:* EDEX is not indicated for use in women or pediatric patients. *Geriatric Use:* In clinical studies, geriatric patients required, on average, higher minimally effective doses and had a higher rate of lack of effect (optimum dose not determined). Overall differences in safety were not observed between geriatric patients and younger patients. Geriatric patients should be dosed and titrated according to the same DOSAGE AND ADMINISTRATION recommendations as younger patients, and the lowest possible effective dose should always be used.

ADVERSE REACTIONS: EDEX, administered in doses ranging from 1 to 40 mcg per injection for periods up to 24 months, has been evaluated for safety in over 1,065 patients with erectile dysfunction. Discontinuation of therapy due to a side effect in clinical trials was required in approximately 9% of patients treated with EDEX and in <1% of patients treated with placebo. *Local Adverse Reactions:* The following local adverse reactions were reported in studies including 1,065 patients treated with EDEX for up to two years. *Penile Pain:* Penile pain was mild in intensity for 80% of painful injections, moderate in intensity for 16% of painful injections, and severe in intensity for 4% of painful injections. The frequency of penile pain reports decreased over time; forty-one percent of the patients experienced pain during the first 2 months and 3% of the patients experienced pain during months 21-24. *Prolonged Erection/Priapism:* See WARNINGS. *Hematoma/Ecchymosis:* Most cases of hematoma and ecchymosis were attributed to faulty injection technique. Local reactions reported in ≥1% of patients treated during all study periods with EDEX (N=1,065): penile pain during injection (29%); penile pain during erection (35%); penile pain after erection (30%); penile pain-other (11%); prolonged erection >4 ≤6 hours (4%); prolonged erection >6 hours (<1%); bleeding (15%); hematoma (5%); ecchymosis (4%); penile angulation (7%); penile fibrosis (5%); cavernous body fibrosis (2%); Peyronie's disease (1%); faulty injection technique (6%); penis disorder (3%); erythema (2%). *Systemic Adverse Experiences:* Reported in controlled and uncontrolled studies in ≥1% of patients treated for up to 24 months with EDEX (N=1,065): upper respiratory tract infection (5%); influenza-like symptoms (3%); headache (2%); infection (2%); pain (2%); back pain (2%); hypertension (2%); hypertriglyceridemia (2%); myocardial infarction (1%); abnormal ECG (1%); hypercholesterolemia (1%); hyperglycemia (1%); prostate disorder (1%); testicular pain (1%); inguinal hernia (1%); skin disorder (1%); abnormal vision (1%); leg pain (1%); and sinusitis (1%). Hemodynamic changes were observed during clinical studies but did not appear to be dose-dependent. Four patients (<1%) reported clinical symptoms of hypotension such as dizziness or syncope. EDEX had no clinically important effect on serum or urine laboratory tests.

DOSAGE AND ADMINISTRATION: *EDEX in the Treatment of Erectile Dysfunction:* The dosage range is 1 to 40 mcg given as an intracavernous injection over a 5 to 10 second interval. Doses greater than 40 mcg have not been studied. A ½ inch, 27 or 30 gauge needle is generally recommended. The patient should not exceed the optimum EDEX dose which was determined in the doctor's office. Use the lowest possible effective dose. *Initial Titration in Physicians Office:* Follow the initial titration instructions that appear in the product package insert. Dosage titration instructions differ depending on erectile dysfunction etiology. *At-Home (Maintenance Therapy) Dosing Instructions:* Properly instruct and train the patient in the self-injection technique, and instruct the patient on the appropriate needles to use for reconstitution and injection. Instruct the patient to discard any needles which become bent as these needles may break. Carefully assess the patient's skills and competence with this procedure. The dose selected for self-injection therapy should provide an erection that is satisfactory for sexual activity and is maintained for no longer than 1 hour. Reduce the dose if the erection lasts longer than 1 hour. Use the lowest effective dose. Initiate self-injection therapy at home with the dose that was determined in the physician's office. Dose adjustment may be required and should be made only after consultation with the physician. Exercise careful and continuous follow-up of patients on self-injection therapy especially for initial self-injections. Recommended injection frequency is no more than 3 times weekly, with at least 24 hours between uses. Instruct the patient in the proper disposal of the syringe, needles, and single-use vial. See the patient every 3 months during self-injection therapy to assess treatment and, if needed, to adjust the dose. Instruct the patient to follow the enclosed patient information pamphlet. **Preparation of Solution:** Refer to product package insert for reconstitution instructions. **Stability:** Refer to product package insert for stability information.

CAUTION: Federal law prohibits dispensing without prescription.

Mfd for:
SCHWARZ PHARMA
Milwaukee, WI 53201

By Abbott Laboratories
North Chicago, IL 60064
6/96

References:
1. Data on file; Schwarz Pharma, Inc.
2. *Red Book Update*, June 1997.

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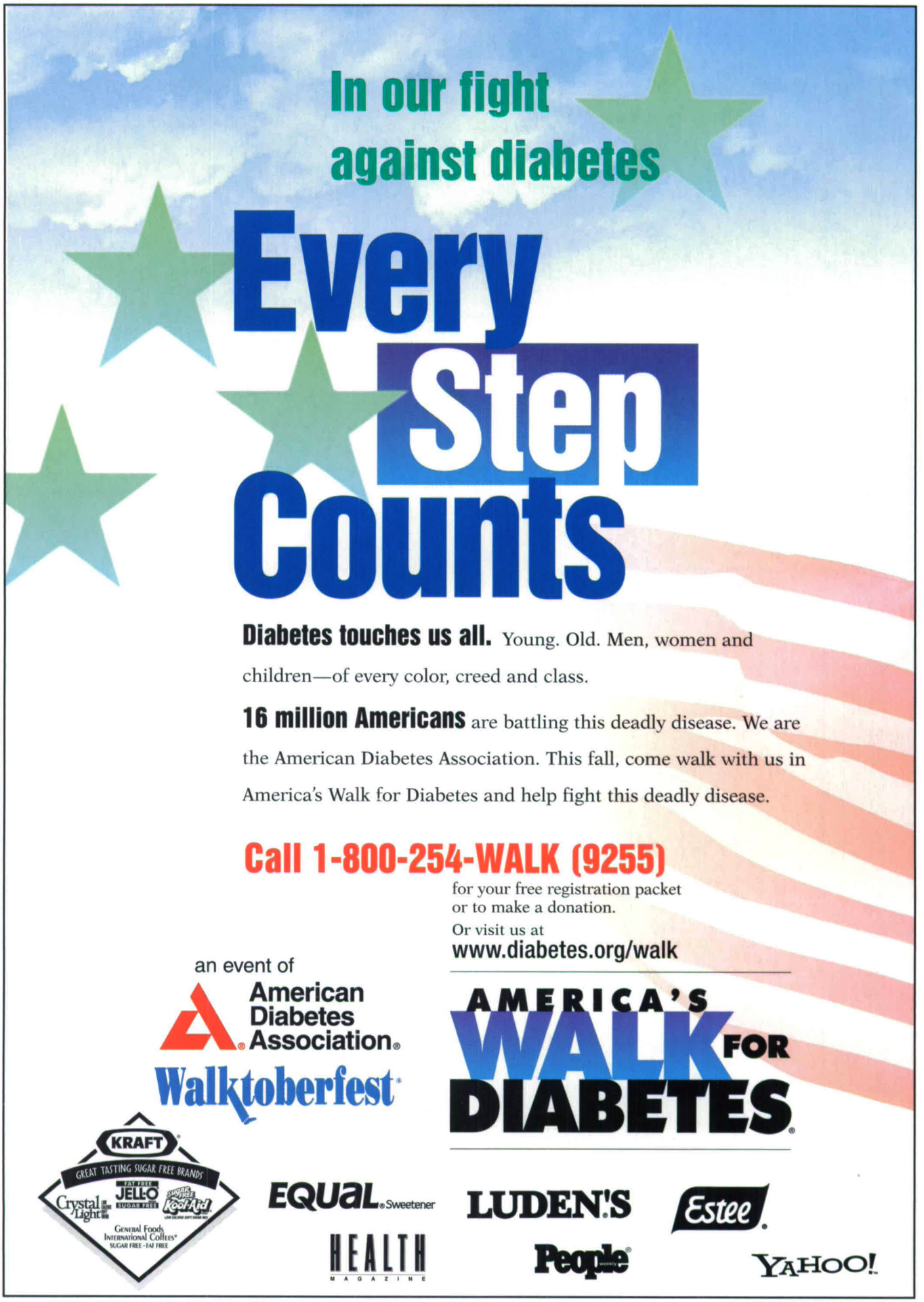
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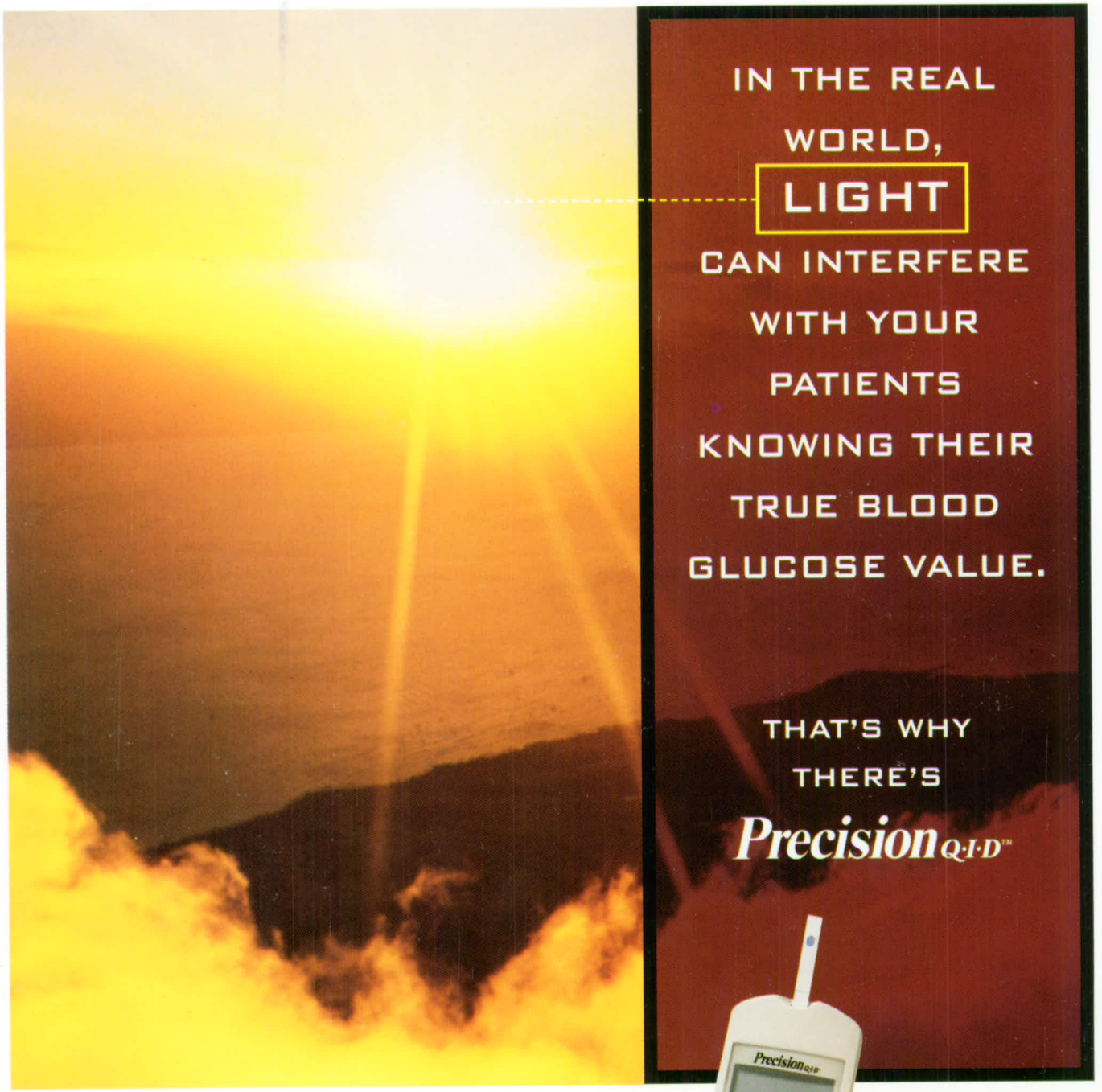

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