HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PRASTERA® safely and effectively. See full prescribing information for PRASTERA®.

PRASTERA® prasterone oral softgels 200mg are for oral use only.

INDICATIONS AND USAGE

PRASTERA® prasterone 200 mg oral softgels are indicated in female patients with mild to moderate, active (SLEDAI ≥2) systemic lupus erythematosus (SLE) to restore serum 5-dehydroandrosterone sulfate to levels typical of women without SLE. In Phase III clinical trials in female patients with mild to moderate active SLE, prasterone 200 mg was associated with reduced risk of flare (§14.1), reduced risk of breast cancer (§6.5) and reduced risk of death from any cause (§6.4).

DOSAGE AND ADMINISTRATION

Recommended dose: one softgel daily. (§2)

DOSAGE FORMS AND STRENGTHS

200mg oral softgel capsules supplied in a convenience package with ibuprofen oral tablets 400mg. (§3)

CONTRAINDICATIONS

Known hypersensitivity to any of its ingredients. (§4)

Undiagnosed abnormal genital bleeding. (§4)

Known, suspected or history of breast cancer. (§4, §6.5)

History of, or known, deep vein thrombosis, pulmonary embolism, arterial thromboembolic disease (e.g., stroke, myocardial infarction). (§4)

Hypercholesterolemia or ischemic heart disease. (§4, §7.2.4)

Hepatic or renal impairment (pharmacokinetic data lacking). (§4, §7.2)

Breast-feeding or known or suspected pregnancy. (§4)

History of psychiatric disorder. (§4, §8)

WARNINGS AND PRECAUTIONS

PRASTERA® is not intended for use in nursing or pregnant women, children and males. (§§4, 9)

PRASTERA® use may be prohibited by certain athletic anti-doping regulations. (§9.5)

PRASTERA® may in certain patients elevate serum levels of 5-dehydroepiandrosterone, testosterone or estrogen above the normal range for healthy, non-afflicted women of similar age. Periodic measurement of serum hormones is prudent. (§7.2.1)

Hypertension may occur with prasterone treatment. Monitor blood pressure closely. (§6.3.2)

ADVERSE REACTIONS

The most common adverse event with PRASTERA® is acne. This is generally treatable with topical anti-acne medication. (§6.1) Another common adverse reaction is hirsutism. Both acne and hirsutism are reversible on cessation of prasterone. (§6.1)

To report SUSPECTED ADVERSE REACTIONS, contact 1 (855) FLARE-FREE or FDA (1-800-FDA-1088 or *www.fda.gov/medwatch*) or your doctor.

DRUG INTERACTIONS

PRASTERA® may interact with certain psychiatric drugs. (§8) Co-administration with testosterone, estrogens or DHEA is not recommended. (§§7.1, 7.2.1, 8, 10, 16.3)

USE IN SPECIFIC POPULATIONS

Not recommended for use in nursing nor pregnant women, pediatric patients, nor men (safety data is lacking). (§9)

See § 16 for PATIENT COUNSELING INFORMATION.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Oral prasterone (200mg per day) in female patients with active systemic lupus erythematosus (SLE) was in several blinded, placebo-controlled randomized clinical studies been associated with reduced risk of auto-immune flare, §§6.2, 14.1.1, reduced risk of breast cancer §6.4 and reduced risk of death from any cause, §§6.5, 14.2.

Patients with SLE may have depressed serum levels of prasterone. Oral prasterone has been shown to restore SLE patients' serum levels. Prastera® is intended for use in patients for whom medical evaluation shows a depressed serum level of prasterone and thus a distinctive need for exogenous prasterone. Prastera® is to be used under medical supervision, for a patient receiving active and ongoing medical supervision, wherein the patient obtains medical care on a recurring basis for, among other things, instructions on the use of this product.

Prastera® does not cure, treat, mitigate or prevent SLE. To the contrary, *patients taking Prastera® will continue to have SLE, and thus may continue to require other appropriate therapy*.

2 DOSAGE AND ADMINISTRATION

2.1 General Instructions

Recommended dose: one 200mg oral softgel daily, with or without food.

2.2 Special Precautions

None.

3 DOSAGE FORMS AND STRENGTHS

Prastera® is provided as oral softgels. Each softgel contains 200mg of prasterone (≥98% pure). Other ingredients: soybean oil USP, soy lecithin NF, gelatin NF, beeswax USP, titanium dioxide USP, polysorbate 80, silicon dioxide, FD&C Blue.

4 CONTRAINDICATIONS

Prastera® oral softgels should not be used in patients with any of the following conditions: (a) Known hypersensitivity to prasterone, DHEA, testosterone, estrogens or any component of Prastera® oral prasterone softgels. §4.1. (b) Undiagnosed abnormal genital bleeding. (c) Known, suspected, or history of breast cancer. §6.5. (d) Active deep vein thrombosis, pulmonary embolism or history of these conditions. (e) Active arterial thromboembolic disease (for example, stroke and myocardial infarction), or a history of these conditions. §6.3.2. (f) Hypercholesterolemia, §7.2.4, or ischemic heart disease. (g) Liver disease or renal impairment (pharmacokinetic data lacking). (h) Known or suspected pregnancy; breast-feeding (safety data lacking). (i) History of psychiatric disorders (risk of exacerbation). The risk of mania may be increased during concomitant use with antidepressants (tricyclic or SSRIs) and/or alcohol, or with high prasterone doses, or in patients with a history of mood disorders.

4.1 Allergy Warning

Prastera® oral softgels contain soy oil and soy lecithin. No milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts.

5 WARNINGS & PRECAUTIONS

PRASTERA® is not intended for use in children, nor males, nor women who are breastfeeding, pregnant, or who expect to become pregnant. §9. Monitoring of blood pressure, serum lipids, serum sex hormones is prudent. *See* Clinical Laboratory Evaluation, §§7.2.1, 7.2.4.

6 ADVERSE REACTIONS

The most-frequent adverse reactions observed in placebo-controlled, blinded clinical studies GL94-01, GL95-01, GL95-02 and GLB96-01 are as follows:

6.1 Increased Risk of Acne and Hirsutism

Acne was the most frequently reported adverse event. The second most-frequent adverse event was hirsutism. Acne and hirsutism were both reversible on cessation of prasterone therapy. In addition, both were more likely to be reported early in treatment; patients who had not developed these within the first 6 months of exposure are less likely to develop them later.

6.2 Reduced Risk of Myalgia and Other Flare Symptoms

Placebo-treated patients had higher incidences of myalgia, joint disorder, anorexia, nasal ulcers and LE skin rash than did prasterone-treated patients. These differences may be due to the decreased risk of flare observed in prasterone-treated patients. §14.1.

6.3 Other Common Adverse Events

No adverse events increase in frequency with longer duration of treatment. The Table displays all adverse events reported in a frequency of 10% or greater from either the 200 mg dose group or the placebo group for the pooled double-blind phases of Studies GL94-01 and GL95-02. Because the number of patients who received prasterone 100 mg was substantially fewer, adverse events for this group are only presented for those adverse events which were reported in ≥ 10% of either placebo or prasterone 200 mg patients.

ADVERSE EVENTS WITH FREQUENCY ≥10%*
(pooled GL94-01 and GL95-02 results)

COSTART TERM	Placebo N=256	200mg N=253
Rash	77 (30.1%)	93 (36.8%)
Acne	39 (15.2%)	91 (36.0%) **
Arthralgia	95 (37.1%)	88 (34.8%)
Asthenia	70 (27.3%)	68 (26.9%)
Headache	76 (29.7%)	60 (23.7%)
Arthritis	58 (22.7%)	57 (22.5%)
Myalgia	79 (30.9%)	55 (21.7%) **
Pain Abdomen	34 (13.3%)	41 (16.2%)
Flu Syndrome	46 (18.0%)	40 (15.8%)
Stomatitis Ulcer	50 (19.5%)	38 (15.0%)
Hirsutism	6 (2.3%)	36 (14.2%) **
Fever	39 (15.2%)	36 (14.2%)
Depression	33 (12.9%)	35 (13.8%)
Alopecia	48 (18.8%)	35 (13.8%)
Infection	37 (14.5%)	26 (10.3%)
Sinusitis	33 (12.9%)	22 (8.7%)
Pain Chest	27 (10.5%)	22 (8.7%)

*Frequency > 10% in either prasterone 200 mg or placebo patients. ** P< 0.05, Placebo vs. prasterone 200 mg. For adverse events occurring in < 10% of patients, the following showed an absolute difference of at least 3% between placebo or prasterone 200 mg, or, if less than 3% difference, the difference was significant ($p < 0.05$):

ADVERSE EVENTS WITH FREQUENCY <10% AND AT LEAST A 3% OR A SIGNIFICANT DIFFERENCE

COSTART TERM	Placebo N=256	prasterone 200 mg N=253
Less Frequent in Prasterone		
Anorexia	10 (3.9%)	2 (0.8%) **
Nasal Septum Disorder (nasal ulcers)	14 (5.5%)	5 (2.0%) **
Rash Lupus Erythematosus	13 (5.1%)	4 (1.6%) **
Joint Disorder	14 (5.5%)	4 (1.6%) **
More Frequent in Prasterone		
Creatinine Increase	0 (0.0%)	6 (2.4%)**
Hypertension	7 (2.7%)	20 (7.9%) **
Hematuria	1 (0.4%)	9 (3.6%) **
Insignificant Difference		
Back Pain	16 (6.3%)	24 (9.5%)
Pharyngitis	14 (5.5%)	6 (2.4%)
Dyspnea	22 (8.6%)	11 (4.3%)
Lymphadenopathy	21 (8.2%)	12 (4.7%)

(pooled GL94-01 and GL95-02 results)
** P< 0.05, Placebo vs. prasterone 200 mg.

The pattern of adverse events in clinical study GLB96-01 showed a similar, but not identical pattern.

ADVERSE EVENTS REPORTED BY ≥ 10% OF EITHER TREATMENT GROUP
(GLB96-01)

	Placebo N= 59	Treatment N= 61
Arthralgia	37 (62.7%)	39 (63.9%)
Acne *	17 (28.8%)	36 (59.0%)*
Pharyngitis	32 (54.2%)	34 (55.7%)
Myalgia	24 (40.7%)	28 (45.9%)
Headache *	37 (62.7%)	26 (42.6%)*
Pain Abdomen	25 (42.4%)	23 (37.7%)
Asthenia	19 (32.2%)	18 (29.5%)
Cough Increase	18 (30.5%)	18 (29.5%)
Dizziness	19 (32.2%)	15 (24.6%)
Pain Chest	11 (18.6%)	14 (23.0%)
Dyspnea	8 (13.6%)	14 (23.0%)
Rash	16 (27.1%)	14 (23.0%)
Fever	17 (28.8%)	13 (21.3%)
Alopecia	8 (13.6%)	13 (21.3%)
Pain	8 (13.6%)	11 (18.0%)
Diarrhea	11 (18.6%)	11 (18.0%)
Rhinitis	13 (22.0%)	11 (18.0%)
Stomatitis Ulcer	17 (28.8%)	10 (16.4%)
Pain Back	10 (16.9%)	9 (14.8%)
Edema	6 (10.2%)	9 (14.8%)
Injury Accident	6 (10.2%)	8 (13.1%)
Insomnia	7 (11.9%)	8 (13.1%)
Pruritus	7 (11.9%)	8 (13.1%)
Infection*	15 (25.4%)	6 (9.8%)*
Dry Eye	10 (16.9%)	6 (9.8%)
Vomit	8 (13.6%)	5 (8.2%)
Peripheral Edema	8 (13.6%)	5 (8.2%)
Rash Lupus Erythematosus	7 (11.9%)	5 (8.2%)
Conjunctivitis	7 (11.9%)	5 (8.2%)
Nausea	9 (15.3%)	4 (6.6%)

*P-value<0.05, Treatment vs. Placebo, chi-square test.

6.3.1 Hypertension

Hypertension was reported as an adverse event more frequently in the prasterone 200 mg group than placebo. When measures of increased (changed) blood pressure were included, there appeared to be no difference between the groups. Whether prasterone increases hypertension is thus not clear.

6.4 Reduced Risk of Death

The risk of death from any cause was five times higher in the placebo group than the treatment group in the GL94-01, GL95-01 and GL95-02 clinical studies (pooled data). The placebo groups had 6 deaths in 77 patients (7.8%); the treatment groups (pooled treatment and cross-over) had 8 deaths in 495 patients (1.6%).

6.5 Reduced Risk of Breast Cancer

Treatment was associated with reduced breast cancer risk in the GL94-01, GL95-01 and GL95-02 studies (pooled data). Breast cancer incidence was 1 in 336 patient-years (0.29%) for placebo and 3 in 1573 patient-years (0.19%) for prasterone (pooled treatment and cross-over).. For women at least 45 years of age, breast cancer risk was 1 in 24 patient-years (4.2%) for placebo and 3 in 206 patient-years (1.5%) for prasterone treatment and cross-over patients.

6.6 Other Serious Adverse Events

Adverse events assessed as "severe" occurred in similar frequencies in treatment and placebo groups. Although the patient numbers are small, abdominal pain reported as a severe adverse event occurred in 6 treated 200 mg patients, 2 treated 100mg patients, and no placebo patients. Serious adverse events occurred in 39 200 mg, 7 100 mg, and 47 placebo patients participating in GL94-01 and GL95-02. However, only 3 serious adverse events were considered possibly related, 2 in the placebo group (one suicide and one patient with menomettrorhagia) and one in 200 mg (a patient with an acute psychosis)..

SEVERE ADVERSE EVENTS OCCURRING IN AT LEAST 2 PATIENTS*
(GL94-01 and GL95-02)

COSTART TERM	Placebo N=256	prasterone 200 mg N=253
Asthenia	22 (8.6%)	22 (8.7%)
Headache	11 (4.3%)	8(3.2%)
Arthralgia	6 (2.3%)	6 (2.4%)
Pain Abdomen	0 (0%)	6 (2.4%)
Rash	5 (2.0%)	6 (2.4%)
Arthritis	2 (0.8%)	5 (2.0%)
Dyspnea	1 (0.4%)	4 (1.6%)
Depression	4 (1.6%)	2 (0.8%)
Diabetes Mellitus	0 (0%)	2 (0.8%)
Emotional Lability	0 (0%)	2 (0.8%)
Infection	0 (0%)	2 (0.8%)
Myalgia	5 (2.0%)	2 (0.8%)
Pain	1 (0.4%)	2 (0.8%)
Pain Chest	4 (1.6%)	2 (0.8%)
Paresthesia	1 (0.4%)	2 (0.8%)
Pleural Disorder	1 (0.4%)	2 (0.8%)
Vasculitis	0 (0%)	2 (0.8%)
Joint Disorder	2 (0.8%)	1 (0.4%)
Peripheral Edema	2 (0.8%)	0 (0%)
Sepsis	2 (0.8%)	0 (0%)
Cyst	2 (0.8%)	0 (0%)
Thinking Abnormal	2 (0.8%)	0 (0%)

*Frequency at least 2 patients in either prasterone 200 mg or placebo.

7 SAFETY

7.1 Relationship Of Dose To Safety

Neither adverse events nor laboratory values showed a dose relationship.

7.2 Clinical Laboratory Evaluation

In the trials, treatment was associated with a dose-related increase in testosterone and a decrease in serum complement (C3) not associated with renal dysfunction, a slight increase in 24-hour urine protein excretion and an early but not progressive decrease in serum lipids (primarily HDL-C and triglycerides. It would be prudent to follow NCEP guidelines and monitor lipids.

7.3 Post-Marketing Experience

The following adverse reactions have been reported with unregulated dietary supplements containing DHEA. The identity, purity and strength of the product was not always known. It is therefore not possible to establish a causal relation to prasterone exposure. Benign premature atrial contractions and occasional premature ventricular contractions. Sahelian (1998) Hepatitis in a patient with high anti-nuclear antibody (ANA) titers; causality is uncertain. Buster (1992) Manic reactions..Dean (2000); Pies (2000).

8 DRUG INTERACTIONS

There is no known pharmacokinetic effect (bioavailability, pharmacokinetics, or pharmacodynamics) of prasterone on prednisone or hydroxychloroquine, with the possible exception of increasing the magnitude of a decrease in triglycerides seen with hydroxyquinoline.

Prasterone may theoretically interact with one or more of the following drugs: carbamazepine, phenothiazines, citalopram; escitalopram; clozapine, conjugated estrogens; estherified estrogens; estradiol; estradiol cypionate; estropipate; ethinyl estradiol, fluoxetine, fluvoxamine; haloperidol, lithium, loxapine, molindone, olanzapine, paroxetine, quetiapine, risperodone, sertraline, testosterone, triazolam and valproic acid..

9 SPECIFIC POPULATIONS

9.1 Males

The placebo-controlled, double-blind clinical studies involved women. Use in men at this time is not recommended because data is lacking.

9.2 Patients with Active SLE Disease

The GL94-01 and GL95-02 clinical studies showed a difference in responder rates between placebo and prasterone increased with increasing baseline SLEDAI.

9.3 Pregnancy

Safety and effectiveness in nursing and pregnant women has not been established. Use is not recommended.

9.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Use in pediatric patients is not recommended.

9.5 Athletic Anti-Doping

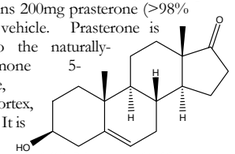
Prasterone use is prohibited by certain athletic anti-doping regulations.

10 OVERDOSE

Oral prasterone of up to 1.6 grams per day has not provoked overdose in post-menopausal women. (Mortola 2000) In case of suspected overdose, treatment should be discontinued and the patient treated symptomatically.

11 DESCRIPTION

Prastera® oral softgels are oblong blue soft gelatin capsules. Each oral softgel contains 200mg prasterone (>98% pure), in a lipophilic vehicle. Prasterone is chemically identical to the naturally-occurring pro-hormone 5-dehydroepiandrosterone, secreted by the adrenal cortex, gonads and brain tissue. It is designated chemically as (3S,8R,9S,10R,13S, 14S)-3-hydroxy-10,13-dimethyl-3,4,7,8,9,10,11,12,13,14,15,16–dodecahydro-1H-cyclopenta[*a*]phenanthren-17(2H)-one. MW=288.424 g/mol. $C_{19}H_{28}O_2$.



12 CLINICAL PHARMACOLOGY

Prastera® softgels are an oral dosage form of pharmaceutical-grade prasterone, chemically identical to prasterone of native human origin, in a lipophilic vehicle.

12.1 Pharmacodynamics

Oral prasterone has been shown to increase serum levels of 5-DHEAS.

12.2 Pharmacokinetics

12.2.1 Time To Peak Concentration

In healthy young women (mean age, 30 years) receiving prasterone 200 mg daily (with prednisone), mean peak plasma levels on day 29 of prasterone and 5-DHEAS were 1.3 mcg/dL (13 ng/mL) and 942 mcg/dL (9.4 mcg/mL), and occurred in 2 hours and 2.4 hours, respectively, after administration. After a single 200 mg dose, mean serum levels of 5-DHEAS increased 21-fold in women (to 7.5 mcg/mL) relative to baseline levels.

12.2.2 Absorption

During two weeks of daily administration (200 mg), plasma levels (and times to peak levels) of both 5-dehydroepiandrosterone and its sulfated metabolite did not change significantly in either women or men, indicating a lack of accumulation.

12.2.3 Distribution

Approximately 10% to 20% of prasterone is bound to serum protein; approximately 80% to 90% of 5-DHEAS is bound to protein. 5-DHEAS penetrates the blood-brain barrier; cerebro-spinal fluid levels of 5-DHEAS range from 0.2% to 5% of corresponding plasma levels.

12.2.4 Metabolism

Oral prasterone is sulfated to 5-DHEAS ester in the intestine and liver by sulfotransferases. Prasterone and 5-DHEAS are converted in peripheral tissues to androstenedione, androsterone sulfate, estradiol, estriol and estrone, dihydrotestosterone, 7-oxo-prasterone, and testosterone.

12.2.5 Excretion

Prasterone (200mg dose) elimination half-life: young women, 11 hours; in elderly women, the elimination half-life progressively declined, from about 12 hours (day 1), to 9 hours (day 8), to 7 hours (day 15). 5-DHEAS half-life: young women, 12 hours; elderly women, 24-27 hours.

12.2.6 Special Populations

Pharmacokinetics has not been assessed in low body weight nor obese patients.

13 PRE-CLINICAL TOXICOLOGY

The non-clinical literature indicates that prasterone may be either chemo-protective or carcinogenic, depending on the model.

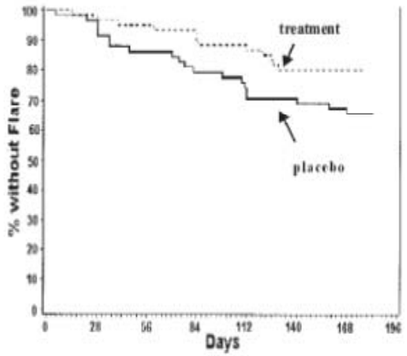
14 CLINICAL STUDIES

The placebo-controlled studies (GL94-01, GL95-01, GL95-02 and GLB96-01) had very different study designs and efficacy endpoints. Pooling of efficacy data is thus not meaningful. Consequently, results are presented by individual study.

14.1 Reduction In Risk Of Flare

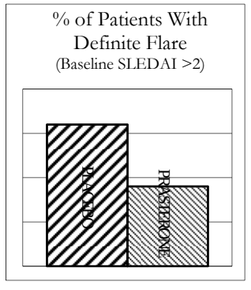
14.1.1 Clinical Study GLB96-01

GLB96-01 was a six month study of prasterone (200mg daily) in Asian women (mean age = 32 years); 97% had baseline SLEDAI score >2. The treatment group (n = 60) had a somewhat higher baseline SLEDAI than did the placebo group (n = 59). The treatment group significantly had fewer patients with at least one definite flare. The number of patients with definite flares in the treatment group was 46.0% less than in the placebo group (18.3% vs. 33.9%, p = 0.044 with survival analysis using Cox model).



14.1.2 Clinical Study GL95-02

Study GL95-02 was a 12 month, multi-center, randomized, parallel group, double-blind, placebo-controlled study of prasterone (200mg daily) in women (n = 346) with active SLE (SLAM score ≥7 excluding ESR, SLEDAI score >2) receiving ≤10 mg/day prednisone (or its equivalent of other cortico-steroids). A secondary efficacy variable (flare) was defined as a modified SELENA definition flare. Three hundred eighty one (381) patients were randomized, of whom 346 were in the per-protocol population. For all patients, 47/176 (27%) of placebo and 37/170 (22%) of prasterone patients experienced a definite flare.



For the subset of patients with a baseline SLEDAI>2, treated patients had a 23.7% decrease in the risk of experiencing at least one definite flare, compared to placebo. During the study period, 41/133 (31%) of placebo patients and 31/132 (23.5%) of prasterone patients experienced a definite flare. *See* bar chart.

For patients with a baseline SLEDAI>2, treated patients had a 23.7% decrease in the risk of experiencing at least one definite flare, compared to placebo (p=0.201, log-rank test for time to first definite flare).

14.2 Reduction In Risk of Death

In the GL95-02 study (discussed above), five placebo patients died, and no prasterone-treated patients died. These data show a statistically significant and clinically meaningful reduction in risk of death by any cause. In the GL94-01, GL95-01 and GL95-02 clinical trials (pooled data), the prasterone treated group (including prasterone-treated crossover patients) experienced 8 deaths among 495 patients, or a risk of death of 1.62%. In contrast, the placebo group experienced 6 deaths among 77 patients, or a risk of death of 7.80%.

14.2.1 Clinical Study GL94-01

Study GL94-01 compared the proportion of patients achieving sustained reduction of daily corticosteroid dose, without worsening of signs and symptoms of SLE ("Responders"), in placebo (n = 64) and prasterone 200 mg (n = 64) groups for about 7 months.

For all randomized patients, 26/64 (41%) placebo and 35/64 (55%) prasterone 200 mg patients responded: a strong trend in favor of prasterone (p = 0.110). For patients with baseline SLEDAI >2, 13/45 (29%) placebo and 23/45 (51%) prasterone 200mg patients responded (p = 0.031).

15 HOW SUPPLIED / DOSAGE AND HANDLING

Prastera® softgels 200mg are oblong blue soft, liquid filled gelatin capsules.

Store at not more than 25° C (77° F). Excursions are permitted to 15° C to 30° C (59° F to 86° F). *See United States Pharmacopoeia*, Controlled Room Temperature. Protect from excessive moisture or humidity. Dispense in a tight, light-resistant container as defined in USP/NF, using a child-resistant closure system, accompanied by a Patient Insert and in a convenience pack together with a blister strip of ibuprofen 400mg oral tablets.

NDC 55607-400-10

Keep out of reach of children.

Manufactured for:
Health Science Funding, LLC
55 Madison Avenue, 4th floor
Morristown, NJ 07960
info@healthsciencefunding.com

16 PATIENT COUNSELING INFORMATION

See Medication Guide (§17) for specific patient instructions.

16.1 Patient / Caregiver Instructions

Inform patients of the following information before initiating therapy with PRASTERA® and periodically during the course of on-going therapy. Encourage patients to read the Medication Guide that accompanies each prescription dispensed, prior to using PRASTERA®.

16.2 Benefits

Oral prasterone 200 mg / day reduced the risk of auto-immune flare, §§6.2, 14.1, and significantly reduced the risk of death, §§6.4, 14.2, in placebo-controlled, randomized, blinded clinical studies (GL94-01, GL95-01, GL95-02 and GLB96-01) in female patients with Systemic Lupus Erythematosus. Results observed in clinical trials may not, however, reflect the rates observed in practice.

PRASTERA® does not cure, mitigate, treat or prevent the patient's underlying SLE. To the contrary, **the patient will continue to have SLE**. The patient therefore should continue to be monitored by a physician and should continue other therapy (e.g., prednisone, NSAID) as believed appropriate.

Oral prasterone reduced the risk of auto-immune flare and death. See above. PRASTERA® may not, however, make the patient feel significantly different on a day-to-day basis. This does not mean PRASTERA® is not working; it may take at least six months of continuous therapy to achieve a statistically-significant reduction in risk of flare and death. §14.

16.3 Other Medications

PRASTERA® is a synthetic form of 5-dehydroepiandrosterone. PRASTERA® should not be combined with dietary supplements containing "DHEA" or "dehydroepiandrosterone."

PRASTERA® is a precursor to testosterone and estrogens. If PRASTERA® is used in conjunction with testosterone or estrogens, levels of serum testosterone and estrogens should be monitored closely to assure levels do not exceed the range seen in healthy women of similar age.

16.4 Adverse Reactions

PRASTERA® may cause acne. This acne is reversible on cessation of prasterone therapy, and may be treateable by a topical anti-acne drug. You may request a Prastera® convenience kit which includes a topical anti-acne drug.

PRASTERA® may cause hirsutism, reversible on cessation of prasterone therapy.

PRASTERA® may cause hypertension, §6.3.2, and/or changes in serum lipids, §7.2.4, or serum hormone levels, §7.2.1. These should be monitored, and are reversible on cessation of prasterone therapy.

16.5 Pregnancy

Instruct patients who are nursing, pregnant or intending to become pregnant, not to use PRASTERA®.

Manufactured for:
Health Science Funding, LLC
55 Madison Avenue, 4th floor
Morristown, NJ 07960
info@healthsciencefunding.com

Rev. Nov. 2015

17 MEDICATION GUIDE

Prasterone is a naturally occurring pre-hormone secreted by your adrenal cortex. SLE attacks your adrenal cortex. Women with SLE thus often have depressed levels of prasterone.

Your doctor has prescribed PRASTERA® to supplement your body's level of this naturally occurring pre-hormone. Use it exactly as your doctor tells you. You may not feel much different taking it. This does not mean that it is not working, so keep taking it unless your doctor tells you not to, or you feel you are having an adverse reaction to it.

In clinical studies, oral prasterone reduced patients' risk of flare, breast cancer and death. Your PRASTERA® does not, however, cure your SLE. Thus, even while taking your PRASTERA®, you will continue to have SLE. You therefore should continue to see your doctor and continue other therapy they believe appropriate.

PRASTERA® may cause acne. If this happens, you can ask your doctor to give you a prescription for a PRASTERA® kit which includes a mild topical anti-acne treatment. And, acne should go away simply by discontinuing PRASTERA®.

PRASTERA® may cause unwanted body hair. This is reversible by discontinuing PRASTERA®.

PRASTERA® may cause abdominal pain, hypertension, and/or changes in serum lipids or serum hormone levels; your doctor may want to monitor these.

Tell your doctor what other drugs or dietary supplements you are taking. If you are taking PRASTERA®, you should not use any dietary supplement containing "DHEA" or "dehydroepiandrosterone."

If you are pregnant, intending to become pregnant, or are nursing, do not use PRASTERA®.

Store your PRASTERA® at not more than 25° C (77° F), and protect from excessive moisture or humidity. Keep out of reach of children.

For advice about suspected side effects, call your doctor. You may report suspected side effects to your doctor, or the FDA at 1 (800) 332-1088, or to your pharmacist, 1 (855) FLARE-FREE.