FOR TYPE II DIABETICS
LIFE IS DEMANDING
ENOUGH...
GLUCOTROL® (glipizide) provides patients with insulin when needed, responding on demand to meals and rising blood sugar.¹

GLUCOTROL, with insulin on demand, controls blood sugar quickly and effectively—all day and all night.¹

GLUCOTROL works in response to meals; returning insulin to near-normal levels once the meal challenge subsides.¹,²

When diet alone fails in NIDDM...°

Glucotrol (glipizide) 5-mg and 10-mg Scored Tablets

* Non-insulin-dependent diabetes mellitus. As with all sulfonylureas, hypoglycemia may occur.

Pfizer
Pratt Pharmaceuticals

Please see brief summary of prescribing information on last page.
FOR TYPE II DIABETES, TODAY'S LIFE DEMANDS INSULIN ON DEMAND

When diet alone fails in NIDDM...

For Type II Diabetes

INSULIN ON DEMAND RESPONSES TO MEALS—
AND REMAINS AT BASAL LEVELS DURING FASTING

Day 1 (with meals)

<table>
<thead>
<tr>
<th>Time (Hours)</th>
<th>Glucolotin Dose</th>
<th>Blood glucose (mg/100 mL)</th>
<th>Plasma insulin (µU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>0</td>
<td>70</td>
<td>55</td>
</tr>
</tbody>
</table>

Day 2 (without meals)

<table>
<thead>
<tr>
<th>Time (Hours)</th>
<th>Glucolotin Dose</th>
<th>Blood glucose (mg/100 mL)</th>
<th>Plasma insulin (µU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>0</td>
<td>100</td>
<td>25</td>
</tr>
</tbody>
</table>

The effect of fasting on blood sugar levels was measured in a 2-day study of six NIDDM patients whose blood sugar levels had been controlled by a single daily dose of 5 to 10 mg of GLUCOLOTIN. On the first day, patients were given 1 meal per day. On the second, they received no food. Patients received their usual dose of GLUCOLOTIN at the start of each day.


Brief Summary of Prescribing Information:

INDICATIONS AND USAGE: Glucolotin is indicated as an adjunct to diet for the control of hyperglycemia in patients with non-insulin-dependent diabetes mellitus (NIDDM, Type II) as an adequate trial of dietary therapy has been unsuccessful.

CONTRAINDICATIONS: GLUCOLOTIN is contraindicated in patients with known hypersensitivity to this drug or with diabetic ketoacidosis, severe renal failure, or severe hepatic impairment.

SPECIAL WARNINGS AND PRECAUTIONS: The use of drugs to control diabetes mellitus must be individualized, and the patient's response closely monitored. The patient should be instructed in the proper management of insulin therapy and in the proper use of the dosage forms available.

The efficacy and safety of GLUCOLOTIN have not been established in children or in diabetic patients with severe renal or hepatic impairment. The use of GLUCOLOTIN in these patients is not recommended.

Additional information is available in the prescribing information. This information is provided as a service to our customers and is subject to change without notice. It is not intended for use in the diagnosis or treatment of specific medical conditions. The information is intended as a guide to assist in the management of patients with diabetes mellitus. The information is not a complete substitute for the medical advice of a qualified physician.

When diet alone fails in NIDDM...

Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible.

Some patients with Type II diabetes may benefit from the addition of a sulfonylurea to diet therapy. It is important to note that the addition of a sulfonylurea to diet therapy does not substitute for insulin therapy.

It is important to provide patient education and self-monitoring to all patients treated with insulin. This is particularly important in patients taking GLUCOLOTIN, as it may be associated with increased risk of hypoglycemia.

In clinical trials, patients treated with GLUCOLOTIN were at increased risk of hypoglycemia compared to patients treated with diet alone. However, the incidence of hypoglycemia was not statistically significant. The risk of hypoglycemia is associated with the degree of glycemic control achieved. The incidence of hypoglycemia may be reduced by decreasing the dose of GLUCOLOTIN or by increasing the dose of the sulfonylurea.

Hypoglycemia: In clinical trials, patients treated with GLUCOLOTIN were at increased risk of hypoglycemia compared to patients treated with diet alone. However, the incidence of hypoglycemia was not statistically significant. The risk of hypoglycemia is associated with the degree of glycemic control achieved. The incidence of hypoglycemia may be reduced by decreasing the dose of GLUCOLOTIN or by increasing the dose of the sulfonylurea.

Gastrointestinal: Gastric intolerance, diarrhea, nausea, and vomiting were common in patients treated with GLUCOLOTIN. These symptoms were usually mild to moderate in severity.

Dermatologic: Allergic skin reactions including urticaria, rash, or pruritus have been reported in patients treated with GLUCOLOTIN. In clinical trials, these reactions have been mild to moderate in severity.

Endocrine: Cases of hyperthyroidism and the development of antithyroid antibodies have been reported in patients treated with GLUCOLOTIN. These cases have been mild to moderate in severity.

DOSAGES AND ADMINISTRATION: The initial dose of GLUCOLOTIN should be 5 mg orally once or twice daily as a single or divided dose. The dose should be increased by 5-mg increments every 3 to 7 days until the desired effect is achieved.

The usual dose range is 5 to 10 mg orally once or twice daily as a single or divided dose. The dose should be increased by 5-mg increments every 3 to 7 days until the desired effect is achieved. The dose may be increased by 5-mg increments every 3 to 7 days until the desired effect is achieved. The dose may be increased by 5-mg increments every 3 to 7 days until the desired effect is achieved. The dose may be increased by 5-mg increments every 3 to 7 days until the desired effect is achieved.

CAUTION: Federal law prohibits dispensing without prescrip|tio

More detailed professional information is available on request.

Revised Jan 1993

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Pratt Pharmaceuticals
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NEW LOW-DOSE
LOZOL®
INDAPAMIDE TABLETS
1.25 MG

A LITTLE MEANS A LOT

TO THE OLDER PATIENT WITH MILD TO MODERATE HYPERTENSION

Efficacy comparable to higher doses of indapamide with the benefits of a lower once-daily dose∗.

Favorable metabolic profile† — no effect on lipids, only 2% incidence of clinical hypokalemia‡.

Less patient discontinuation than with placebo

Side-effect profile compatible with other antihypertensive agents

Please see brief summary of prescribing information on this page.

LOZOL® (indapamide) 1.25 mg and 2.5 mg tablets

INDICATIONS: LOZOL® (indapamide) is indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs, and for the treatment of salt and fluid retention associated with congestive heart failure.

Use in Pregnancy: See PRECAUTIONS.

CONTRAINDICATIONS: Anuria, hypokalemia, or other sodium-depleted states.

WARNINGS: Intermittent course of severe hypertension, accompanied by hypokalemia, has been reported with 1.25 mg and 5 mg indapamide in patients with advanced renal disease. Hypokalemia may be prevented or corrected by potassium supplements or by potassium-sparing diuretics. Hypokalemia may also occur in patients on a sodium-restricted diet. In addition, patients should be observed for clinical signs of fluid or electrolyte imbalance, such as hypokalemia, hypochloremic alkalosis, or hyperkalemia. The risk of hypokalemia secondary to diuretics and salt restriction is increased with larger doses, in edematous patients, with severe renal disease, and with concomitant use of corticosteroids or ACTH.

INTERACTIONS: The administration of diuretics with potassium-sparing agents, other potassium-sparing diuretics, or other potassium-sparing agents may result in hyperkalemia. The concurrent use of potassium-sparing diuretics, especially in elderly, can predispose to hypokalemia. Potassium-sparing diuretics may also cause a paradoxical effect by enhancing hypokalemia. Hypokalemia can sensitise or exaggerate the response of the heart to the toxic effects of digitals, such as increased ventricular irritability. Diuretics impair renal function in patients with renal insufficiency. The administration of diuretics in renal insufficiency or acute renal failure is contraindicated.

ADVERSE REACTIONS: Most adverse effects have been mild and transient. From placebo-controlled studies with indapamide 1.25 mg, adverse reactions with 7.5 mg cumulative incidence headache, indigestion, pain, back, chest, nausea, vomiting, dizziness, metallic taste, constipation, diarrhea, nausea, paraesthesia, nervousness, hypokalemia, cough, pharyngitis, rhinitis, conjunctivitis. All other clinical adverse reactions occurred at an incidence of <1%. In controlled clinical trials of up to six weeks in duration, 9% of patients receiving indapamide 1.25 mg, 5% of patients receiving indapamide 2.5 mg, and 3% of patients receiving indapamide 5 mg had at least one potassium level below 3.5 mEq/L. In the indapamide 1.25 mg group, about 40% of those patients who reported hypokalemia as a laboratory adverse event returned to normal serum potassium levels without intervention. Hypokalemia with concurrent clinical signs or symptoms occurred in 2% of patients receiving indapamide 1.25 mg. From Phase II placebo-controlled studies and long-term controlled clinical trials with LOZOL® 1.25 mg or 2.5 mg, adverse reactions with 5% cumulative incidence: headache, dizziness, nausea, vomiting, diarrhea, nausea, paraesthesia, rash, urticaria, breathlessness, increased body weight, hyperkalemia, hematuria, hypokalemia, hyperkalemia, hyperuricemia, hyperuricemia. In excess in serum 5.0 mg or more.

∗ In a controlled clinical trial, at 4 weeks the changes in systolic/diastolic BP with 5 mg of indapamide was -10.5/5.5 mm Hg vs -5.0/2.5 mm Hg with LOZOL® 1.25 mg.
† Because of the diuretic effects of LOZOL® 1.25, changes in certain electrolytes and blood chemistries can occur. Serum electrolytes and blood chemistries should therefore be monitored.‡ 19.6% of patients had potassium values less than 3.4 mEq/L. Only 7.5% had potassium levels below 3.2 mEq/L, and less than 1% fell below 3.0 mEq/L. Mortality changes at higher doses of indapamide may be greater.

This Is How BPH Feels
New Indication

Release the Grip
of BPH

For Fast, Effective Relief

- Hytrin can begin providing symptom relief in two weeks.¹

- Approximately 70% of patients experience an increase in urinary flow and improvement in symptoms.¹

- In an ongoing open-label study, the improvements in symptoms and flow rates have been sustained for up to 30 months.¹,²

Hytrin Rapidly Reduces Symptoms of BPH

![Graph showing mean total symptom scores over weeks for placebo and Hytrin.](image)

A randomized, double-blind, placebo-controlled, multicenter trial in men with qualifying symptoms given either placebo or Hytrin titrated to response (max. 10 mg/day).¹

From a Wide Range of Symptoms

- Hytrin significantly improves the most common and often bothersome symptoms of BPH:¹
  - weak stream
  - frequency
  - nocturia

- Hytrin also significantly improves dribbling, intermittency, hesitancy, and the sensation of incomplete emptying.¹

Begin Prescribing Hytrin

HYTRIN® (terazosin HCl)

For fast, effective relief

© 1993; Abbott Laboratories

Please see brief summary of prescribing information for Hytrin on last page of this advertisement.
For Fast, Effective Relief

Hytrin improves peak flow rates\textsuperscript{1,2}

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{flow_rate_graph}
\caption{Change in peak flow rates with Hytrin vs baseline. Improvements were statistically significant at all points of measurement.\textsuperscript{2}}
\end{figure}

Hytrin Relaxes Prostatic Smooth Muscle

- Symptomatic BPH has two underlying components:\textsuperscript{1,3}
  - Static (increased prostate size)
  - Dynamic (increased smooth muscle tone)

- Prostate size does not correlate with symptom severity.\textsuperscript{1}

Smooth muscle surrounds the urethra\textsuperscript{3,4}

- Hytrin relaxes smooth muscle tone of the prostate and bladder neck, thereby relieving the symptoms of BPH.\textsuperscript{5-7}

\textbf{Begin Prescribing Hytrin}

\textbf{HYTRIN (terazosin HCl)}

For fast, effective relief

Please see brief summary of prescribing information for Hytrin on last page of this advertisement.
New Indication
Relieve the Pre
ssures of BPH

Well-Tolerated Therapy

- Discontinuation due to adverse events was not significantly different from that of placebo.¹
- Adverse events that occurred significantly more often with Hytrin than with placebo were dizziness (9.1%), asthenia (7.4%), postural hypotension (3.9%), somnolence (3.6%), nasal congestion/rhinitis (1.9%), and impotence (1.6%).¹
- Incidence of syncope (0.6%) was not significantly different from that of placebo.¹
- Prior to starting therapy, patients should be screened for prostate cancer. Hytrin had no significant effect on PSA.¹

In BPH patients, the mean diastolic blood pressure reductions were -15.1 mm Hg in hypertensives; -2.2 mm Hg in normotensives; -1.8 mm Hg in controlled hypertensives.²

Hytrin, like other α₁-blockers, can cause marked lowering of blood pressure, especially postural hypotension and syncope.¹

Caution should be observed when Hytrin tablets are administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to avoid the possibility of developing significant hypotension. Dosage reduction and retitration of either agent may be necessary.¹

*Begin Prescribing Hytrin
HYTRIN
(terazosin HCl)
For fast, effective relief

Please see brief summary of prescribing information for Hytrin on last page of this advertisement.
New Indication

Fast, Effective Relief

Once a Day — One Price

- Initial dose: 1 mg at bedtime, should not be exceeded.
- Subsequent once-daily doses should be titrated in a stepwise fashion to 2 mg, 5 mg, or 10 mg for desired relief.
- If Hytrin is discontinued for several days, reinstitute therapy by using the initial dosing regimen.
- Hytrin, like other alpha₁-blockers, can cause marked lowering of blood pressure. Monitor blood pressure during initial administration or titration to minimize the risk of hypotension and syncope.¹
- All tablet strengths are identically priced.
- Call 1-800-ABBOTT-5 to receive the Hytrin Free Start™ sample program.

References

Begin Prescribing Hytrin

HYTRIN
(terazosin HCl)

For fast, effective relief

Please see brief summary of prescribing information for Hytrin on last page of this advertisement.
BRIEF SUMMARY FOR BENIGN PROSTATIC HYPERPLASIA (BPH) CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

HYTRIN® (terazosin hydrochloride)

INDICATIONS AND USAGE

For the treatment of symptomatic benign prostatic hyperplasia (BPH) in males, and syncoca in association with the first dose or first few days of therapy. A similar effect can be anticipated if therapy is interrupted for 24 hours or longer. The safety and efficacy of HYTRIN in smaller children has not been established.

CONTRAINDICATIONS

Patients known to be hypersensitive to terazosin hydrochloride.

WARNINGS

Syncoca and "First-Dose" Effect: HYTRIN, tablets, like other alpha-adrenergic blocking agents, can cause marked lowering of blood pressure, especially in postural hypotension, and syncoca in association with the first dose or first few days of therapy. A similar effect can be anticipated if therapy is interrupted for 24 hours or longer. The safety and efficacy of HYTRIN in smaller children has not been established.

Drugs Interactions: In controlled trials, HYTRIN tablets have been added to diuretics, and several beta-adrenergic blockers; no unex¬ected reactions have been noted. The use of HYTRIN has also been used in patients on a variety of concomitant therapies; while these were not formal interaction studies, no unanticipated adverse effects were observed. The use of HYTRIN has been used concomitantly in at least 50 patients on the following drugs or drug classes: 1) analgesics/inflammatory (e.g., aspirin, ibuprofen, naproxen sodium, ketoprofen, indomethacin); 2) antibiotics (e.g., erythromycin, trimethoprim and sulfamethoxazole); 3) antihypertensive agents (e.g., atenolol, nitrofurantoin, hydrochlorothiazide, and propranolol); 4) antihyperglycemic agents (e.g., sulfinpyrazone, glyburide); 5) antipsychotic agents (e.g., amitriptyline, thioridazine); 6) corticosteroids; 7) gastrointestinal agents (e.g., acetaminic, naproxen, drugs that alter hepatic enzymes (e.g., diazepam).

In a study (n=24) where terazosin and verapamil were administered concomitantly, terazosin's mean AUC0-∞ increased 11% after the first verapamil dose and after 3 weeks of verapamil treatment it increased by 24% with increased concentrations in Cmax (25%) and Cmin (39%) means. Terazosin AUC0-∞ increased from 1.3 hours to 0.8 hours after 3 weeks of verapamil treatment. Statistically significant differences were not observed in terazosin's maximum concentration level with and without terazosin. In a study (n=97) where terazosin and captopril were administered concomitantly, plasma disposition of captopril was not influenced by com¬comitant administration of terazosin and captopril maximum plasma concentrations increased linearly with dose as steady state effects were noted for terazosin plus captopril (see Dosage and Administration).

Carcinogenesis, Mutagenesis, Impairment of Fertility: HYTRIN was evaluated for carcinogenic potential when evalu¬ated in vivo and in vitro (the Ames test, in vitro cytogenetics, the dominant lethal test in mice, in vitro Chinese Hamster Ovary chromosomal and gene mutation assay). HYTRIN was administered in the fed state at doses of 8, 40, and 250 mg/kg/day for two years, was associated with a statistically significant increase in benign adrenal medullary tumors in male rats given 200 mg/kg/day and adrenal medullary at 50 mg/kg/day. This dose is 54 times the maximum recommended human dose of 20 mg/kg/day in a mouse carcinogenicity assay, of increased total tumor incidence in either species, and of proliferative adrenal lesions in female rats, suggests a male rat species-specific effect. Numerous other diverse pharmacological and chemical compounds have also been associated with the increased adrenal medullary tumors in male rats without supporting evidence for carcinogenicity in man.

The effect of TERAZOSIN on fertility was assessed in a standard fertility/reproductive performance study in which male and female rats were administered oral doses of 8, 30 and 100 mg/kg/day, respectively. At the higher dose, TERAZOSIN was not oncogenic in mice when administered in feed for 2 years at a maximum tolerated dose of 32 mg/kg/day. The absence of mutagenicity in a battery of in vitro and in vivo assays, which included the forward mutation assay, indicated that HYTRIN is highly protein bound; therefore, dialysis may not be of benefit.

If HYTRIN administration is discontinued for several days, therapy should be reinitiated using the initial dosing regimen.

BENIGN PROSTATIC HYPERPLASIA

Initial Dose: At bedtime is the starting dose for all patients, and this dose should not be exceeded as an initial dose. Patients should be closely followed during initial administration in order to minimize the risk of severe hypertensive response.

Subsequent Doses: Those doses should be increased in a stepwise fashion to 2 mg, 5 mg, or 10 mg once daily to achieve the desired improvement of symptoms and/or flow rates. Doses of 10 mg and 20 mg are generally not recommended for clinical response. Therefore, treatment with 10 mg for a minimum of 4-6 weeks may be required to assess whether a beneficial response has been achieved or whether the patient may not achieve a clinical response despite appropriate titration. Although some additional patients responded at a 20 mg dose, there was an increased number of patients who stopped treatment due to adverse effects. Therefore, doses of 10 mg daily if patients were unable to achieve the desired response were considered.

Use with Other Drugs: Caution should be observed when HYTRIN tablets are administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to patients with hypertension or at risk for hypertensive crisis. The use of HYTRIN in this group of patients is not recommended. When using HYTRIN tablets and other antihypertensive agents concomitantly, dosage reduction and titration of either agent may be necessary (see Precautions).

Reference: Ref. 03-4434-87-BPH Revised: September 1993

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Once-A-Day

NEW Adalat®
nifedipine
EXTENDED RELEASE TABLETS
30mg, 60mg & 90mg

Real Value for Real People with Hypertension

Real Therapeutic Value
- The benefits of long-acting nifedipine therapy for hypertension

Real Human Value
- Convenient, well-tolerated therapy
- Peripheral edema and headache were the most common dose-related adverse events reported; flushing/heat sensation, dizziness, and fatigue/asthenia were all reported at an incidence of 4%

Real Economic Value
- Lower price (AWP) than Procardia XL® 30 mg, 60 mg and 90 mg—potential 25% savings†

*Not indicated for angina. Take on an empty stomach. Careful titration may be necessary when switching between Procardia XL® and Adalat® CC.
†Calculations based on suggested Average Wholesale Price (AWP).
‡Procardia XL is a registered trademark of Pfizer Labs Division. Pfizer Inc.
Please see brief summary of Prescribing Information on back of this page.

Candidate Profile
Name: Helen R.
Age: 72
Residence: New York City
Pretreatment BP: 170/102
Marital Status: widowed
Health Ins: Medicare

“Save as much as $111† a year?
That’s bus fare to work for three months.”
Start with*  RX

Tritrate, if necessary*  RX

Real People, Real Needs, Real Value

Although nifedipine has been used safely in patients with renal dysfunction and has been reported to exert a beneficial effect in certain cases, rare, reversible elevations in BUN and serum creatinine have been reported in patients with pre-existing chronic renal insufficiency. The relationship to nifedipine therapy is uncertain in most cases but probably in some.

Dry Irritation: Beta-adrenergic blocking agents (See WARNINGS). Nifedipine was well tolerated when administered in combination with a beta blocker in 127 hypertensive patients in a placebo-controlled clinical trial. However, there have been anecdotal literature reports suggesting that the combination of nifedipine and beta-adrenergic blocking drugs may increase the likelihood of congestive heart failure, exacerbation of angina pectoris, and edema in patients with advanced disease.

Diet: Since there have been isolated reports of patients with advanced diastolic hypertension who may experience exacerbation of their hypertension, it is prudent to monitor patients closely, with special attention to symptoms of congestive heart failure, and edema.

Drug Interactions: beta-adrenergic blocking agents (See WARNINGS). Nifedipine was well tolerated when administered in combination with a beta blocker in 127 hypertensive patients in a placebo-controlled clinical trial. However, there have been anecdotal literature reports suggesting that the combination of nifedipine and beta-adrenergic blocking drugs may increase the likelihood of congestive heart failure, exacerbation of angina pectoris, and edema in patients with advanced disease.

Diet: Since there have been isolated reports of patients with advanced diastolic hypertension who may experience exacerbation of their hypertension, it is prudent to monitor patients closely, with special attention to symptoms of congestive heart failure, and edema.

Nifedipine can be metabolized by the liver and the renal route; therefore, patients with renal impairment may require lower doses or more frequent doses of nifedipine. The dosage adjustment should be based on the individual patient's needs and response to therapy.

Nifedipine can be metabolized by the liver and the renal route; therefore, patients with renal impairment may require lower doses or more frequent doses of nifedipine. The dosage adjustment should be based on the individual patient's needs and response to therapy.

The following adverse events have been reported rarely in patients given nifedipine in other formulations: allergic hepatitis, leukopenia, anemia, arthritis with ARA (-), depression, erythema multiforme, cutaneous dermatitis, fever, gingival hyperplasia, gynecomastia, leukopenia, mood changes, muscle cramps, nervousness, paranoid syndrome, purpura, shakiness, sleep disturbances, syncope, tachycardia, thromboembolism, transient blindness of the peak plasma level, tremor, urticaria.

Nifedipine can be metabolized by the liver and the renal route; therefore, patients with renal impairment may require lower doses or more frequent doses of nifedipine. The dosage adjustment should be based on the individual patient's needs and response to therapy.

The following adverse events have been reported rarely in patients given nifedipine in other formulations: allergic hepatitis, leukopenia, anemia, arthritis with ARA (-), depression, erythema multiforme, cutaneous dermatitis, fever, gingival hyperplasia, gynecomastia, leukopenia, mood changes, muscle cramps, nervousness, paranoid syndrome, purpura, shakiness, sleep disturbances, syncope, tachycardia, thromboembolism, transient blindness of the peak plasma level, tremor, urticaria.

Nifedipine can be metabolized by the liver and the renal route; therefore, patients with renal impairment may require lower doses or more frequent doses of nifedipine. The dosage adjustment should be based on the individual patient's needs and response to therapy.

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† As with other NSAIDs, the most frequent complaints relate to the GI tract. In patients treated chronically with NSAID therapy, serious GI toxicity such as perforation, ulceration, and bleeding can occur.


63848N Please see adjacent page for brief summary of prescribing information.
Now, for allergic rhinitis...

ONCE DAILY FOR RELIEF

ONCE DAILY Nasacort Nasal Inhaler (triamcinolone acetonide)

Once daily for convenience
Once daily for comfort
Once daily for unsurpassed safety

Turns patient complaints...into patient compliance

Please see brief summary of prescribing information on adjacent page.
ONCE DAILY FOR RELIEF

Nasacort
(triamcinolone acetonide)

For Intra Nasal Use Only
Shake well before using.

BRIEF SUMMARY

CONTRAINDICATIONS: Hypersensitivity to any of the ingredients of this preparation contraindicates its use.

WARNINGS: The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency and, in addition, some patients may experience symptoms of withdrawal, e.g., joint and/or muscular pain, lassitude and depression. Patients previously treated for prolonged periods with systemic corticosteroids and transferred to topical corticosteroids should be carefully monitored for acute adrenal insufficiency in response to stress. In those patients who have asthma or other clinical conditions requiring long-term systemic corticosteroid treatment, too rapid a decrease in systemic corticosteroids may cause a severe exacerbation of their symptoms.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can be more serious or even fatal course in children on immunosuppressant doses of corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

The use of Nasacort Nasal Inhaler with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (HPA) suppression compared to a therapeutic dose of either one alone. Therefore, Nasacort Nasal Inhaler should be used with caution in patients already receiving alternate-day prednisone treatment for any disease.

PRECAUTIONS: General: In clinical studies with triamcinolone acetonide administered intranasally, the development of localized infections of the nose and pharynx with Candida albicans has rarely occurred. When this occurs, it may require treatment with appropriate local therapy and discontinuance of treatment with Nasacort Nasal Inhaler.

Trixamcinolone acetonide administered intranasally has been shown to be absorbed into the systemic circulation in humans. Patients with active rhinitis showed absorption similar to that found in normal volunteers. Nasacort at 440 mcg/day for 42 days do not measurably affect adrenal function as measured by corticotropin test. In this same study prednisone 10 mg/day significantly reduced adrenal response to ACTH over the same period (see CLINICAL TRIALS section).

Nasacort Nasal Inhaler should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract or in patients with untreated fungal, bacterial, or systemic viral infections or ocular herpes simplex. Because of the inhibitory effect of corticosteroids on wound healing in patients who have experienced recent nasal septal ulcers, nasal surgery or trauma, a corticosteroid should be used with caution until healing has occurred.

When used at excessive doses, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, Nasacort Nasal Inhaler should be discontinued slowly, consistent with accepted procedures for discontinuing oral steroid therapy.

Information for Patients: Patients being treated with Nasacort Nasal Inhaler should receive the following information and instructions.

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to obtain medical advice immediately.

Patients should use Nasacort Nasal Inhaler at regular intervals since its effectiveness depends on its regular use. A decrease in symptoms may occur as soon as 12 hours after starting steroid therapy and generally can be expected to occur within a few days of initiating therapy in allergic rhinitis. The patient should take the medication as directed and not exceed the prescribed dosage. The patient should contact the physician if symptoms do not improve after three weeks, or if the condition worsens. Nasal irritation and/or burning or stinging after use of the spray occur only rarely with this product. The patient should contact the physician if they occur.

For the proper use of this unit and to attain maximum improvement, the patient should read and follow the accompanying patient instructions carefully. Because the amount dispersed per puff may not be consistent, it is important to shake the canister well. Also, the canister should be discarded after 100 actuations.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Male and female rats which were administered oral triamcinolone acetonide at doses as high as 15 mg/kg/day (110 mcg/m2/day, calculated as a surface area basis) exhibited no evidence of impaired fertility. The maximum human dose, for comparison, is 6.3 mcg/kg/day (240 mcg/m2/day). However, a few female rats which received medically toxic doses of 8 or 15 mcg/kg/day 60 mcg/m2/day or 110 mcg/m2/day, respectively, as calculated on a surface area basis) exhibited dystocia and prolonged delivery.

Developmental toxicity, which included fetal resorptions and stillbirths and decreases in pup body weight and survival, also occurred at at least maternally toxic doses (2.5 - 15.0 mcg/kg/day or 20 - 110 mcg/m2/day, as calculated on a surface area basis). Reproducive performance of female rats and effects on fetuses and offspring were comparable between groups that received placental and non-toxic or marginally toxic doses (0.5 and 1.0 mcg/kg-day or 3.8 and 7.0 mcg/m2/day).

Pregnancy: Category C. Triamcinolone acetonide has been shown to be teratogenic in rats and rabbits. Teratogenic effects, which occurred in both species at 10 and 20 mcg/kg/day (5 and 10 mg/m2/day) and in the rat at 60, 120, 360, 690 and 1200 mcg/m2/day in the rabbit, as calculated on a surface area basis, included a low incidence of cleft palate and/or internal hydrocephaly and axial skeletal defects. Teratogenic effects, including CNS and cranial anomalies, have also been observed in the offspring of rats treated with triamcinolone (0.5 mg/kg/day) for 13 days during gestation and for the first 10 days postpartum. Pregnant women should not receive triamcinolone acetonide if it can be avoided. However, triamcinolone acetonide has been also shown to have teratogenic effects in rabbits. Maternal body weight of 70 kg. Administration of aerosol by inhalation to pregnant rats and rabbits produced embryotoxic and fetotoxic effects which were comparable to those produced by administration by other routes. There are no adequate and well-controlled studies in pregnant women. Triamcinolone acetonide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Experience with oral corticosteroids since their introduction in pharmacologic as opposed to physiologic doses suggests that risk of adverse effects to the fetus is lower than experience from corticosteroids than humans, in addition, because there is a natural increase in glucocorticoid production during pregnancy, most women will require a lower exogenous steroid dose and many will not need corticosteroid treatment during pregnancy.

Nonteratogenic Effects: Hypocalcemia may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observed.

Nursing Mothers: It is not known whether triamcinolone acetonide is excreted in human milk. Because other corticosteroids are excreted in human milk, caution should be exercised when Nasacort Nasal Inhaler is administered to nursing women.

Pediatric Use: Safety and effectiveness have not been established in children below the age of 12. Oral corticosteroids have been shown to cause growth suppression in children and teenagers, particularly when higher doses over prolonged periods. A child on corticosteroids who appears to have growth suppression, the possibility that they are particularly sensitive to this effect should be considered.

ADVERSE REACTIONS: In controlled and uncontrolled studies, 1257 patients received treatment with intranasal triamcinolone acetonide. Adverse reactions are based on the 56% of patients who received a product similar to the marketed Nasacort nasal. These patients were treated for an average of 48 days (range 1 to 117 days). The 145 patients enrolled in uncontrolled studies treated from 1 to 603 days (average 330 days).

The most prevalent adverse experience was headache, being reported by approximately 18% of the patients who received Nasacort. Nasal irritation was reported by 2.8% of the patients receiving Nasacort. Other nasopharyngeal side effects were reported by fewer than 5% of the patients who received Nasacort and included dry mucous membranes, nasal congestion, mouth dryness, sneezing, and epistaxis. The complaints do not usually interfere with treatment and in the controlled and uncontrolled studies approximately 1% of patients have discontinued because of these nasal adverse effects.

In the event of accidental overdose, an increased potential for these adverse experiences may be expected, but systemic adverse experiences are unlikely (see OVERDOSAGE section).

OVERDOSAGE: Acute overdose with this dosage form is unlikely. The acute topical application of the entire 15 mg of the canister would most likely cause nasal irritation and headache. It would be unlikely to see any systemic adverse effects if the nasal application of the 15 mg of triamcinolone acetonide was administered all at once.

Caution: Federal (U.S.A.) law prohibits dispensing without prescription. Please see product circular for full prescribing information.


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Please consult Brief Summary of Prescribing Information on last page of this advertisement.
BRIEF SUMMARY

That qualified excretion

PRECAUTIONS:

arrhythmias, prior women:

following with tumors

Chest, Tests:

signs

hémiplégie

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others

None

(Imitrex)

did

situations

There

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there

60

elderly

sensations,

Rarities

Relief:

Bone

neuropathy;

nausea;

Gastrointestinal:

difficulties in concentration, disturbances of smell, hyperesthesia, dysaesthesia, simultaneous hot and cold sensations, tickling sensations, dysaesthesia, yawning, reduced appetite, hunger, and dysphoria.

Respiratory:

infection was dyspnea. Rare were influenza, diseases of the lower respiratory tract, and hiccoughs.

Dermatological: Infection were erythema, pruritus, and skin rash; shingles and eruptions. Rare was skin tenderness.

Urgent? Rare were dysuria, frequency, dysmenorrhea, and renal calculi.

Miscellaneous: Infection were miscellaneous laboratory abnormalities, including minor disturbances in liver function tests, “sensitivities” to effect, and hypersensitivity; various rare symptoms. Rare was fever.

Postmarketing Experience: Frequency and causality for sumatriptan are not established for many of the following reports, which come from worldwide postmarketing experience. Episodes of Pneumonitis an anemias; Contraction: renal failure, biliary obstruction, cerebrovascular accident, dysphasia, subarachnoidal hemorhage, and arthritis (articular friction, venous stenosis, and venous stenosis). Hyponatrarity to Imitrex injection has been reported, including anaphylactoid reactions, rash, urticaria, pruritus, erythema, and shortness of breath.

REFERENCES

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*Usual adult dosage is 1200 mg (two 600-mg caplets) once a day. For osteoarthritis patients of low body weight or with milder disease, an initial dosage of one 600-mg caplet once a day may be appropriate.

† Nonsteroidal anti-inflammatory drug.

As with all NSAIDs, the most frequently reported adverse reactions were related to the GI tract: nausea (6%) and dyspepsia (6%). In patients treated with DAYPRO, as with other NSAIDs in the long-term, serious GI toxicity such as bleeding, ulceration, and perforation can occur and patients should be selected accordingly.

Please see brief summary of prescribing information on following page.
All you want in an NSAID

Get DAYPRO
(Oxaprozin)

Adult usual dosage is 1200 mg (two 600-mg caplets) once a day.*

Experience with NSAIDs has shown that starting therapy with maximal doses in elderly patients or those with CHF, hepatic impairment, or mild-to-moderate renal insufficiency is likely to increase the frequency of adverse reactions in such patients.

BRIEF SUMMARY

CONTRAINDICATIONS: Patients with previously demonstrated hypersensitivity to oxaprozin or any of its components or in individuals with the complete or partial syndrome of nasal polyps, angioedema, and bronchospastic reactivity to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs). Severe and occasionally fatal gastrointestinal and/or systemic reactions have been reported in patients receiving NSAIDs, and there have been rare reports of anaphylaxis in patients taking oxaprozin.

WARNINGS: RISK OF GASTROINTESTINAL (GI) ULCERATION, BLEEDING, AND PERFORATION WITH NONSTEROIDAL ANTI-INFLAMMATORY DRUG THERAPY: Serious GI toxicity, such as bleeding, ulceration, and perforation, can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Although minor upper GI problems, such as dyspepsia, are common, and usually develop early in therapy, physicians should remain alert for ulceration and bleeding in patients treated chronically with NSAIDs, even in the absence of previous GI tract symptoms. In patients observed in clinical trials for several months to years, the incidence of serious ulcerative and hemorrhagic complications of serious GI toxicity and what steps to take if they occur. Patients at risk for developing peptic ulceration and bleeding are those with a prior history of serious GI events, alcoholism, smoking, or concurrent use of corticosteroids or other ulcerogenic drugs. Use of an ulcer prophylactic drug is recommended to prevent ulceration or bleeding less well than other individuals, and most spontaneous reports of fatal GI ulceration have involved single-episode treatment with high doses of oxaprozin. The risk of ulceration or bleeding is probably less than that of patients given aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs) for various NSAIDs in causing such reactions. High doses of any NSAID probably carry a greater risk of these reactions.

PRECAUTIONS: In patients with other NSAIDs, borderline elevations of one or more liver tests may occur in up to 15% of patients. These abnormalities may progress, remain essentially unchanged or resolve with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction in patients treated with NSAIDs. In general, the safety of oxaprozin in controlled clinical trials of Daypro in just under 1% of patients. A patient with symptoms and/or signs suggesting liver dysfunction or in whom an abnormal liver test has occurred should be evaluated for evidence of possible liver disease before therapy is started. Daypro, an important factor in the development of more severe hepatic reactions while on therapy with this drug. Severe hepatic reactions including jaundice have been reported with Daypro, and there may be a risk of fatal hepatic reactions with oxaprozin, as has been seen with other NSAIDs. Although such reactions are rare, if abnormal liver tests persist or worsen, clinical signs and symptoms consistent with liver disease develop, or systemic manifestations occur (e.g., jaundice, rash, fever), Daypro should be discontinued. Well-controlled hepatic cirrhosis does not appear to alter the disposition of unbound oxaprozin, so dosage adjustment is not necessary. Caution should be observed in patients with severe hepatic dysfunction, Acute interstitial nephritis, hematuria, and proteinuria have been observed in patients receiving oxaprozin. Daypro can be used in patients with impaired renal function, or patients who are undergoing hemodialysis. However, Daypro should be used slowly in patients with acute or chronic renal failure or in patients who are undergoing hemodialysis. Such patients should be started on doses of 600 mg/day with careful dosage increments as the inflammatory effect is not abolished. Oxaprozin is not cleared because of its high degree of protein binding. Like other NSAIDs, Daypro may worsen fluid retention by the kidneys in patients with uncomplicated cardiac failure due to its effect on prostaglandins. It should be used with caution in patients with a history of hypertension, cardiac decompensation, in patients on chronic diuretic therapy, or in those with conditions predisposing to fluid retention. Oxaprozin has been associated with rash and/or mild photosensitivity in dermatologic testing. An increased incidence of rash on sun-exposed skin was seen in some patients in the clinical trials. Because serious GI tract ulceration and bleeding can occur with warning symptoms, physicians should follow chronically treated patients for the signs and symptoms, and in patients in whom these symptoms are more likely to occur, should institute the treatment of this follow-up. Anemia may occur in patients receiving oxaprozin or other NSAIDs. This may be due to fluid retention, gastrointestinal bleeding, or an incompletely described effect upon erythropoiesis. Patients on chronic diuretic therapy may be at increased risk of this complication of the use of oxaprozin. Oxaprozin should be used cautiously in patients with underlying hemostatic defects or in those who are undergoing surgical procedures where a high degree of hemostasis is needed. The side effects of oxaprozin can cause discomfort, nausea, vomiting, diarrhea, and abdominal pain that may be due to drug therapy may be associated with hemodynamic disturbances and even fatal outcomes. Physicians may wish to discuss with their patients the potential risks and likely benefit of therapy. Daypro has been shown to be effective in the management of osteoarthritis and Daypro may represent an acceptable alternative to both the patient and the physician. Patients receiving Daypro may benefit from physician instruction in the symptoms of the more common or serious side effects of Daypro, but if such symptoms occur, therapy should be discontinued. Opioid analgesics and supportive care following an NSAID overdose. There are no specific antidotes. Gastric decontamination may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. In such cases, the patient should be kept nil per os and the activated charcoal (80 to 100 g in adults, 1 to 2 g/kg in children) with an osmotic cathartic. Forced diuresis, alkalinization of the urine, or hemodialysis would probably not be useful due to the high degree of protein binding of oxaprozin.

*For osteoarthritis patients of low body weight or with milder disease, an initial dosage of one 600-mg caplet once a day may be appropriate.

ADVERSE REACTIONS: The most frequently reported adverse reactions were related to the GI tract. They were nausea (8%) and dyspepsia (8%).

INCIDENCE GREATER THAN 1%: Clinical trials showed that enlarged testes and oligospermia were uncommon.

ADVERSE REACTIONS: The frequency of adverse reactions was found to be less than 1% or was reported rarely.

OVERDOSAGE: No patient experienced either an accidental or intentional overdosage of Daypro in the clinical trials of the drug. Symptoms following acute overdose with other NSAIDs are usually limited to the toxic effects of the drug itself. Daypro is not an enzyme that may be due to drug therapy may be associated with hemodynamic disturbances and even fatal outcomes. Physicians may wish to discuss with their patients the potential risks and likely benefit of therapy. Daypro has been shown to be effective in the management of osteoarthritis and Daypro may represent an acceptable alternative to both the patient and the physician. Patients receiving Daypro may benefit from physician instruction in the symptoms of the more common or serious side effects of Daypro, but if such symptoms occur, therapy should be discontinued. Opioid analgesics and supportive care following an NSAID overdose. There are no specific antidotes. Gastric decontamination may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose. In such cases, the patient should be kept nil per os and the activated charcoal (80 to 100 g in adults, 1 to 2 g/kg in children) with an osmotic cathartic. Forced diuresis, alkalinization of the urine, or hemodialysis would probably not be useful due to the high degree of protein binding of oxaprozin.

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THERE IT IS.

A recent survey of pharmacy directors representing 154 HMOs covering 15.5 million patients showed Naprosyn to be 96% formulary-accepted. That was more than any other branded prescription NSAID.

Contraindicated in patients hypersensitive to naproxen, aspirin, or other NSAIDs. As with other NSAIDs, the most frequent adverse events are gastrointestinal. With chronic NSAID therapy, serious G.I. toxicity such as bleeding, ulceration, and perforation can occur. Rare hepatic and renal reactions have been reported.

YOU MANAGE THE CHOICE

EXPECT SUCCESS FROM

NAPROSYN

(NAPROXEN) 500 mg tablets

Also available in 275 and 500 mg tablets and in suspension 125 mg/5 mL.