A visit to your doctor’s office can be overwhelming. Feeling prepared and organized may help. Print out this guide, answer the questions below, and bring it with you to your next appointment. You and your doctor can work together to determine a breast cancer treatment plan that’s best for you.

VISIT AROMASIN.COM FOR MORE TOOLS AND RESOURCES TO HELP YOU TAKE A MORE ACTIVE ROLE IN YOUR TREATMENT PLAN.

1. Are you experiencing any type of unusual problems or symptoms? If so, please list your symptoms below.

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

2. On average, you get □ hours of sleep each night. Ask your doctor if that is enough.

3. Exercise may help improve mental and physical health. List any activities that you like to do (such as walking or gardening). Ask your doctor if it is recommended to continue these activities and if there are other ways you can stay fit.

______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

4. In the space below, write down any questions you might have for your doctor. During your appointment, write down the responses so you can look back at them later.

<table>
<thead>
<tr>
<th>QUESTION</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Please see Indication and Important Safety Information on reverse and accompanying Full Prescribing Information and Patient Information.
Indication
AROMASIN® (exemestane tablets) is a prescription medicine for:

• Early breast cancer: AROMASIN is indicated for the adjuvant treatment (additional treatment given after the primary or main treatment) of postmenopausal women with estrogen-receptor positive (ER positive) early breast cancer. If switching to AROMASIN, treatment with AROMASIN should begin 2 to 3 years after tamoxifen, at which time tamoxifen should be stopped. Treatment with AROMASIN should continue for 2 to 3 years until a total of 5 years of adjuvant treatment of tamoxifen and AROMASIN have been completed.

• Advanced breast cancer: AROMASIN is indicated for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed after tamoxifen therapy.

Important Safety Information
Do not take AROMASIN if you are allergic to AROMASIN or to anything in it. The active ingredient is exemestane. Do not take AROMASIN if you are pregnant or if you might become pregnant as it may cause birth defects or miscarriage. If you become pregnant while taking AROMASIN, talk to your doctor immediately to learn about the potential risks to the baby. Do not take AROMASIN if you still have menstrual periods. AROMASIN is only for women who are past menopause.

Let your doctor know if you are taking or applying any medication that has estrogen in it, or if you are taking any other medicines or supplements as they can affect how well AROMASIN works.

A serious side effect of AROMASIN is bone loss over time that may increase your risk of osteoporosis and bone fractures. The health of your bones should be carefully monitored by your doctor for any bone loss before and during treatment with AROMASIN. Any bone loss should be treated appropriately.

Before starting to take AROMASIN, have your blood levels checked for Vitamin D deficiency. This is a common condition in women with early breast cancer and should be treated with Vitamin D supplements.

A small number of women had chest pain, heart failure or stroke while taking AROMASIN.

Common side effects of AROMASIN in women with early breast cancer were hot flushes, feeling tired, joint pain, headache, difficulty sleeping and increased sweating. Common side effects of AROMASIN in women with advanced breast cancer were hot flushes, nausea, feeling tired, increased sweating and increased appetite.

Tell your doctor if you have liver or kidney problems.

AROMASIN has risks and benefits. There may be other options. Talk to your doctor to learn more.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Need help paying for your Pfizer medicines?
Pfizer Helpful Answers® may be able to help, regardless of your insurance situation.
Learn how at www.PHAEhelps.com

Please see accompanying Full Prescribing and Patient Information on following pages.
AROMASIN® (exemestane) tablets, oral
Initial U.S. Approval: 1999

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1 INDICATIONS AND USAGE

1.1 Adjuvant Treatment of Postmenopausal Women

AROMASIN is indicated for adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to AROMASIN for completion of a total of five consecutive years of adjuvant hormonal therapy [see Clinical Studies (14.1)].

1.2 Advanced Breast Cancer in Postmenopausal Women

AROMASIN is indicated for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy (14.2).

---

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose

The recommended dose of AROMASIN in early and advanced breast cancer is one 25 mg tablet once daily after a meal.

- adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to AROMASIN for completion of a total of five consecutive years of adjuvant hormonal therapy [see Clinical Studies (14.1)].
- treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy (14.2).

---

3 DOSAGE FORMS AND STRENGTHS

AROMASIN Tablets are round, biconvex, and off-white to slightly gray. Each tablet contains 25 mg of exemestane. The tablets are printed on one side with the number “7663” in black.

---

4 CONTRAINDICATIONS

- Patients with a known hypersensitivity to the drug or to any of the excipients (4.1).
- Women of menopausal endocrine status, including pregnant women (4.2).

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5 WARNINGS AND PRECAUTIONS

5.1 Administration with Estrogen-Containing Agents

5.2 Laboratory Tests

5.3 Reductions in Bone Mineral Density (BMD)

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12 CLINICAL PHARMACOLOGY

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17 PATIENT COUNSELING INFORMATION

17.1 Premenopausal Women

17.2 Other Estrogen-Containing Agents

17.3 Bone Effects

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*Sections or subsections omitted from the full prescribing information are not listed.

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WARNINGS AND PRECAUTIONS

- Reductions in bone mineral density (BMD) over time are seen with exemestane use (5.3).
- Routine assessment of 25-hydroxy vitamin D levels prior to the start of aromatase inhibitor treatment should be performed (5.4).

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ADVERSE REACTIONS

- Early breast cancer: Adverse events occurring in ≥10% of patients in any treatment group (AROMASIN vs. tamoxifen) were hot flushes (21.2% vs. 19.9%), fatigue (16.1% vs. 14.7%), arthralgia (14.6% vs. 8.6%), headache (13.1% vs. 10.8%), insomnia (12.4% vs. 8.9%), and increased sweating (11.8% vs. 10.4%). Discontinuation rates due to AEs were similar between AROMASIN and tamoxifen (6.5% vs. 5.1%). Incidences of cardiac ischemic events (myocardial infarction, angina, and myocardial ischemia) were AROMASIN 1.6%, tamoxifen 0.6%. Incidence of cardiac failure: AROMASIN 0.4%, tamoxifen 0.3% (6.1).
- Advanced breast cancer: Most common adverse events were mild to moderate and included hot flushes (13% vs. 5%), nausea (9% vs. 5%), fatigue (8% vs. 10%), increased sweating (4% vs. 8%), and increased appetite (3% vs. 6%) for AROMASIN and megestrol acetate, respectively (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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DRUG INTERACTIONS

- Strong CYP 3A4 inducers: Concomitant use of strong CYP 3A4 inducers decreases exemestane exposure. Increase the Aromasin dose to 50 mg (2.2, 7).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 05/2014
study in advanced breast cancer patients, CTC grade 3 or 4 elevation of gamma glutamyl transferase without documented evidence of liver metastasis was reported in 2.7% of patients treated with AROMASIN and in 1.8% of patients treated with megestrol acetate.

In early breast cancer patients, elevations in bilirubin, alkaline phosphatase, and creatinine were more common in those receiving exemestane than either tamoxifen or placebo. Treatment-emergent bilirubin elevations (any CTC grade) occurred in 5.3% of exemestane patients and 0.8% of tamoxifen patients on the intergroup Exemestane Study (IES), and in 6.5% of exemestane treated patients vs. 0.3% of placebo treated patients in the 027 study. CTC grade 3-4 increases in bilirubin occurred in 0.9% of exemestane treated patients compared to 0.1% of tamoxifen treated patients. Alkaline phosphatase elevations of any CTC grade occurred in 15.0% of exemestane treated patients on the IES compared to 2.6% of tamoxifen treated patients, and in 13.7% of exemestane treated patients compared to 6.9% of placebo treated patients in study 027. Creatinine elevations occurred in 5.8% of exemestane treated patients vs. 4.3% of tamoxifen treated patients on the IES and in 5.5% of exemestane treated patients and 0% of placebo treated patients in study 027.

5.3 Reductions in Bone Mineral Density (BMD)

Reductions in bone mineral density (BMD) over time are seen with exemestane use. Table 1 describes changes in BMD from baseline to 24 months in patients receiving exemestane compared to patients receiving tamoxifen (IES) or placebo (027). Concomitant use of bisphosphonates, vitamin D supplementation, and calcium was not allowed.

### Table 1. Percent Change in BMD from Baseline to 24 months, Exemestane vs. Control

<table>
<thead>
<tr>
<th></th>
<th>Exemestane</th>
<th>Tamoxifen</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral neck (%)</td>
<td>-4.15</td>
<td>-0.33</td>
<td>-4.57</td>
</tr>
<tr>
<td></td>
<td>-2.59</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

During adjunct treatment with exemestane, women with osteoporosis or at risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry at the commencement of treatment. Monitor patients for bone mineral density loss and treat as appropriate.

6. ADVERSE REACTIONS

AROMASIN was generally well tolerated and adverse events were usually mild to moderate.

In the adjuvant treatment of early breast cancer, adverse events occurring in ≥10% of patients in any treatment group (AROMASIN vs. tamoxifen) were hot flushes (21.2% vs. 19.9%), fatigue (16.1% vs. 14.7%), arthralgia (14.6% vs. 8.6%), headache (13.1% vs. 10.8%), insomnia (12.4% vs. 8.9%), and increased sweating (11.8% vs. 10.4%). Discontinuation rates due to AEs were similar between AROMASIN and tamoxifen (6.3% vs. 5.1%). Incidences of cardiac ischemic events (myocardial infarction, angina, and myocardial ischemia) were AROMASIN 1.6%, tamoxifen 0.6%. Incidence of cardiac failure: AROMASIN 0.4%, tamoxifen 0.3%.

In the treatment of advanced breast cancer, the most common adverse events were mild to moderate and included hot flushes (13% vs. 5%), nausea (9% vs. 5%), fatigue (8% vs. 10%), increased sweating (4% vs. 8%), and increased appetite (3% vs. 6%) for AROMASIN and megestrol acetate, respectively.

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adjuvant Therapy

The data described below reflect exposure to AROMASIN in 2325 postmenopausal women with early breast cancer. AROMASIN tolerability in postmenopausal women with early breast cancer was evaluated in two well-controlled trials: the IES study (14.1) and the 027 study (a randomized, placebo-controlled, double-blind, parallel group study specifically designed to assess the effects of exemestane on bone metabolism, hormones, lipids, and coagulation factors over 2 years of treatment).

The median duration of adjuvant treatment was 27.4 months and 27.3 months for patients receiving AROMASIN or tamoxifen, respectively, within the IES study and 23.9 months for patients receiving AROMASIN or placebo within the 027 study. Median duration of observation after exemestane was 34.5 months and for tamoxifen was 34.6 months. Median duration of observation was 30 months for both groups in the 027 study.

Certain adverse events, which were expected based on the known pharmacological properties and side effect profiles of test drugs, were actively sought through a positive checklist. Signs and symptoms were graded for severity using CTC in both studies. Within the IES study, the presence of some illnesses/conditions was monitored through a positive checklist without assessment of severity. These included myocardial infarction, other cardiovascular disorders, gynecological disorders, osteoporosis, osteoporotic fractures, other primary cancer, and hospitalizations.

AROMASIN was generally well tolerated and adverse events were usually mild to moderate. Within the IES study, discontinuations due to adverse events occurred in 6.3% and 5.1% of patients receiving AROMASIN and tamoxifen, respectively, and in 12.3% and 4.1% of patients receiving exemestane or placebo respectively within study 027.

Deaths due to any cause were reported for 1.3% of the exemestane treated patients and 1.4% of the tamoxifen treated patients within the IES study. There were 6 deaths due to stroke on the exemestane arm compared to 2 on tamoxifen. There were 5 deaths due to cardiac failure on the exemestane arm compared to 2 on tamoxifen.

The incidence of cardiac ischemic events (myocardial infarction, angina, and myocardial ischemia) was 1.6% in exemestane treated patients and 0.6% in tamoxifen treated patients in the IES study. Cardiac failure was observed in 0.4% of exemestane treated patients and 0.3% of tamoxifen treated patients.

Treatment-emergent adverse events and illnesses including all causalities and occurring with an incidence of ≥1% in either treatment group of the IES study during or within one month of the end of the treatment are shown in Table 2.

### Table 2. Incidence (%) of Adverse Events of all Grades and Illnesses Occurring in ≥5% of Patients in Any Treatment Group in Study IES in Postmenopausal Women with Early Breast Cancer

<table>
<thead>
<tr>
<th><strong>Event</strong></th>
<th><strong>AROMASIN</strong></th>
<th><strong>Tamoxifen</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding</strong></td>
<td>5.0 (N=2325)</td>
<td>3.8 (N=2286)</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
<td>8.5</td>
<td>8.7</td>
</tr>
<tr>
<td><strong>General Disorders</strong></td>
<td>16.1</td>
<td>14.7</td>
</tr>
<tr>
<td><strong>Musculoskeletal</strong></td>
<td>14.6</td>
<td>8.6</td>
</tr>
<tr>
<td><strong>Psychiatric</strong></td>
<td>12.4</td>
<td>8.9</td>
</tr>
<tr>
<td><strong>Psychiatric</strong></td>
<td>6.2</td>
<td>5.6</td>
</tr>
<tr>
<td><strong>Skin &amp; Subcutaneous Tissue</strong></td>
<td>11.8</td>
<td>10.4</td>
</tr>
<tr>
<td><strong>Vascular</strong></td>
<td>21.2</td>
<td>19.9</td>
</tr>
<tr>
<td><strong>Vascular</strong></td>
<td>9.8</td>
<td>8.4</td>
</tr>
</tbody>
</table>

1. Graded according to Common Toxicity Criteria; 2. 75 patients received tamoxifen 30 mg daily; 3. Event actively sought.

In the IES study, as compared to tamoxifen, AROMASIN was associated with a higher incidence of events in musculoskeletal disorders and in nervous system disorders, including the following events occurring with frequency lower than 5% (osteoporosis [4.6% vs. 2.8%], osteolysis [3.7% vs. 1.8%], arthralgia [2.4% vs. 0.9%], carpal tunnel syndrome [2.4% vs. 0.2%], and neuropathy [0.6% vs. 0.1%]). Diarrhea was also more frequent in the exemestane group (4.2% vs. 2.2%). Clinical fractures were reported in 94 patients receiving exemestane (4.2%) and 71 patients receiving tamoxifen (3.1%). After a median duration of therapy of about 30 months and a median follow-up of about 52 months, gastric ulcer was observed at a slightly higher frequency in the AROMASIN group compared to tamoxifen (0.7% vs. <1%). The majority of patients on AROMASIN with gastric ulcer received concomitant treatment with non-steroidal anti-inflammatory agents and/or had a prior history.

Tamoxifen was associated with a higher incidence of muscle cramps [3.1% vs. 1.5%], thromboembolism [2.0% vs. 0.9%], endometrial hyperplasia [1.7% vs. 0.6%], and uterine polyps [2.4% vs. 0.4%]. Common adverse events occurring in study 027 are described in Table 3.

### Table 3. Incidence of Selected Treatment-Emergent Adverse Events of all CTC Grades* Occurring in ≥5% of Patients in Either Arm in Study 027

<table>
<thead>
<tr>
<th><strong>Adverse Event</strong></th>
<th><strong>Exemestane</strong></th>
<th><strong>Placebo</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hot flushes</strong></td>
<td>32.9 (N=73)</td>
<td>24.7</td>
</tr>
<tr>
<td><strong>Arthralgia</strong></td>
<td>28.8 (N=73)</td>
<td>28.8</td>
</tr>
<tr>
<td><strong>Increased sweating</strong></td>
<td>17.6</td>
<td>20.6</td>
</tr>
<tr>
<td><strong>Alopecia</strong></td>
<td>15.1 (N=73)</td>
<td>4.1</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>15.1 (N=73)</td>
<td>6.9</td>
</tr>
<tr>
<td><strong>Insomnia</strong></td>
<td>13.7 (N=73)</td>
<td>15.1</td>
</tr>
<tr>
<td><strong>Nausea</strong></td>
<td>12.3 (N=73)</td>
<td>16.4</td>
</tr>
<tr>
<td><strong>Fatigue</strong></td>
<td>11.0 (N=73)</td>
<td>19.2</td>
</tr>
<tr>
<td><strong>Abdominal pain</strong></td>
<td>11.0 (N=73)</td>
<td>13.7</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td>9.8 (N=73)</td>
<td>6.9</td>
</tr>
<tr>
<td><strong>Diarrhea</strong></td>
<td>9.8 (N=73)</td>
<td>1.4</td>
</tr>
<tr>
<td><strong>Dizziness</strong></td>
<td>9.8 (N=73)</td>
<td>9.6</td>
</tr>
<tr>
<td><strong>Dermatitis</strong></td>
<td>8.2 (N=73)</td>
<td>1.4</td>
</tr>
<tr>
<td><strong>Headache</strong></td>
<td>6.9 (N=73)</td>
<td>4.1</td>
</tr>
<tr>
<td><strong>Myalgia</strong></td>
<td>5.5 (N=73)</td>
<td>4.1</td>
</tr>
<tr>
<td><strong>Edema</strong></td>
<td>5.5 (N=73)</td>
<td>6.9</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td>4.1 (N=73)</td>
<td>5.5</td>
</tr>
</tbody>
</table>

* Most events were CTC grade 1–2.
program, only 3% of the patients discontinued treatment with exemestane because of adverse events, mainly within the first 10 weeks of treatment; late discontinuations because of adverse events were uncommon (0.3%).

In the comparative study, adverse reactions were assessed for 358 patients treated with AROMASIN and 400 patients treated with megestrol acetate. Fewer patients receiving AROMASIN discontinued treatment because of adverse events than those treated with megestrol acetate (2% vs. 5%). Adverse events that were considered drug related or of indeterminable cause included hot flashes (13% vs. 5%), nausea (9% vs. 5%), fatigue (8% vs. 10%), increased sweating (4% vs. 8%), and increased appetite (3% vs. 6%) for AROMASIN and megestrol acetate, respectively. The proportion of patients experiencing an excessive weight gain (>10% of their baseline weight) was significantly higher with megestrol acetate than with AROMASIN (17% vs. 8%). Table 4 shows the adverse events of all CTG grades, regardless of causality, reported in 5% or greater of patients in the study treated either with AROMASIN or megestrol acetate.

Table 4. Incidence (%) of Adverse Events of all Grades* and Causes Occurring in >5% of Advanced Breast Cancer Patients in Each Treatment Arm in the Comparative Study

<table>
<thead>
<tr>
<th>Body system and Adverse Event by WHO AR dictionary</th>
<th>AROMASIN 25 mg once daily (N=358)</th>
<th>Megestrol Acetate 40 mg QID (N=400)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomic Nervous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased sweating</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Body as a Whole</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>22</td>
<td>29</td>
</tr>
<tr>
<td>Hot flashes</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Pain</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Influenza-like symptoms</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Edema (includes edema, peripheral edema, leg edema)</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Nervous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>Insomnia</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Anxiety</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Dizziness</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Headache</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>18</td>
<td>12</td>
</tr>
<tr>
<td>Vomiting</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Anorexia</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Constipation</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Increased appetite</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Respiratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Coughing</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

* Graded according to Common Toxicity Criteria

Less frequent adverse events of any cause (from 2% to 5%) reported in the comparative study for patients receiving AROMASIN 25 mg once daily were fever, generalized weakness, paresthesia, pathological fracture, bronchitis, sinussitis, rash, itching, urinary tract infection, and lymphedema.

Additional adverse events of any cause observed in the overall clinical trials program (N = 1058) in 5% or greater of patients treated with exemestane 25 mg once daily but not in the comparative study included pain at tumor sites (8%), asthenia (6%), and fever (5%). Adverse events of any cause reported in 2% to 5% of all patients treated with exemestane 25 mg in the overall clinical trials program but not in the comparative study included chest pain, hyposthesia, confusion, dyspepsia, arthralgia, back pain, skeletal pain, infection, upper respiratory tract infection, pharyngitis, rhinitis, and alopecia.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post approval use of AROMASIN. Because reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune system disorders- hypersensitivity
Hepatobiliary disorders- hepatitis including cholestatic hepatitis
Nervous system disorders- paresthesia
Skin and subcutaneous tissue disorders- acute generalized exanthematous pustulosis, urticaria, pruritus

7 DRUG INTERACTIONS

Drugs That Induce CYP 3A4
Co-medications that induce CYP 3A4 (e.g., rifampicin, phenytoin, carbamazepine, phenobarbital, or St. John’s wort) may significantly decrease exposure to exemestane. Dose modification is recommended for patients who are also receiving a strong CYP 3A4 inducer [see Dosage and Administration (2.2) and Clinical Pharmacology (12.3)].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category X. See “Contraindications” section. AROMASIN can cause fetal harm when administered to a pregnant woman and the clinical benefit to premenopausal women with breast cancer has not been demonstrated. AROMASIN is contraindicated in women who are or may become pregnant. There are no adequate and well-controlled studies of AROMASIN in pregnant women.

In non-clinical studies in rats and rabbits, exemestane was embryotoxic, fetotoxic, and abortifacient. Radioactivity related to 14C-exemestane crossed the placenta of rats following oral administration of 1 mg/kg exemestane. The concentration of exemestane and its metabolites was approximately equivalent in maternal and fetal blood. When rats were administered exemestane from 14 days prior to mating until either day 15 or 20 of gestation, and resuming for the 21 days of lactation, an increase in placental weight was seen at 4 mg/kg/day (approximately 1.5 times the recommended human daily dose on a mg/m2 basis). Prolonged gestation and abnormal or difficult labor was observed at doses equal to or greater than 20 mg/kg/day. Increased resorption, reduced number of live fetuses, decreased fetal weight, and retarded ossification were also observed at these doses. No malformations were noted when exemestane was administered to pregnant rats during the organogenesis period at doses up to 810 mg/kg/day (approximately 320 times the recommended human dose on a mg/m2 basis). Daily doses of exemestane, given to rabbits during organogenesis, caused a decrease in placental weight at 90 mg/kg/day (approximately 70 times the recommended human daily dose on a mg/m2 basis). Abortions, an increase in resorptions, and a reduction in fetal body weight were seen at 270 mg/kg/day. There was no increase in the incidence of malformations in rabbits at doses up to 270 mg/kg/day (approximately 210 times the recommended human dose on a mg/m2 basis).

If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus and the potential risk for pregnancy loss.

8.3 Nursing Mothers

AROMASIN is only indicated in postmenopausal women. However, radioactivity related to exemestane disappeared in rat milk within 15 minutes of oral administration of radiolabeled exemestane. Concentrations of exemestane and its metabolites were approximately equivalent in the milk and plasma of rats for 24 hours after a single oral dose of 1 mg/kg 14C-exemestane. It is not known whether exemestane is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reaction in nursing infants from AROMASIN, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Hepatic Impairment

The AUC of exemestane was increased in subjects with moderate or severe hepatic impairment (Childs-Pugh B or C) [see Clinical Pharmacology (12.3)]. However, based on experience with exemestane at repeated doses up to 200 mg daily that demonstrated a moderate increase in non life-threatening adverse events, dosage adjustment does not appear to be necessary.

8.7 Renal Impairment

The AUC of exemestane was increased in subjects with moderate or severe renal impairment (creatinine clearance <35 mL/min/1.73 m2) [see Clinical Pharmacology (12.3)]. However, based on experience with exemestane at repeated doses up to 200 mg daily that demonstrated a moderate increase in non life- threatening adverse events, dosage adjustment does not appear to be necessary.

10 OVERDOSAGE

Clinical trials have been conducted with exemestane given as a single dose to healthy female volunteers at doses as high as 800 mg and daily for 12 weeks to postmenopausal women with advanced breast cancer at doses as high as 600 mg. These dosages were well tolerated. There is no specific antidote to overdosage and treatment must be symptomatic. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

A male child (age unknown) accidentally ingested a 25-mg tablet of exemestane. The initial physical examination was normal. But blood tests performed 1 hour after ingestion indicated leukocytosis (WBC 25000/mm3 with 90% neutrophils). Blood tests were repeated 4 days after the incident and were normal. No treatment was given.

In mice, mortality was observed after a single oral dose of exemestane of 3200 mg/kg, the lowest dose tested (about 640 times the recommended human dose on a mg/m2 basis). In rats and dogs, mortality was observed after single oral doses of exemestane of 5000 mg/kg (about 2000 times the recommended human dose on a mg/m2 basis) and 3000 mg/kg (about 4000 times the recommended human dose on a mg/m2 basis), respectively.

Convolutions were observed after single doses of exemestane of 400 mg/kg and 3000 mg/kg in mice and dogs (approximately 80 and 4000 times the recommended human dose on a mg/m2 basis), respectively.

11 DESCRIPTION

AROMASIN® Tablets for oral administration contain 25 mg of exemestane, an irreversible, steroidal aromatase inactivator. Exemestane is chemically described as 6-methylendienandrosta-1,4-diene-3,17-dione. Its molecular formula is C21H24O2 and its structural formula is as follows:

The active ingredient is a white to slightly yellow crystalline powder with a molecular weight of 296.41. Exemestane is freely soluble in N,N-dimethylformamide, soluble in methanol, and practically insoluble in water.
Each AROMASIN Tablet contains the following inactive ingredients: mannitol, crospovidone, polyvinylpyrrolidone, cornstarch, magnesium stearate, stearic acid, colloidal silica, silicon dioxide, polyethylene glycol 6000, and sodium starch glycolate, crospovidone, simethicone, polyethylene glycol 6000, sodium starch glycolate, magnesium stearate, simethicone, polyethylene glycol 6000, sucrose, magnesium carbonate, titanium dioxide, methylene blue, and polyvinyl alcohol.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Breast cancer cell growth may be estrogen-dependent. Aromatase is the principal enzyme that converts androgens to estrogens both in pre- and postmenopausal women. While the main source of estrogen (primarily estradiol) is the ovary in premenopausal women, the principal source of circulating estrogens in postmenopausal women is from conversion of transdermally applied androgens (androstenedione and testosterone) to estrogens (estrone and estradiol) by the aromatase enzyme in peripheral tissues. Estrogen deprivation through aromatase inhibition is an effective and selective treatment for some postmenopausal patients with hormone-dependent breast cancer.

Exemestane is an irreversible, steroid-aromatase inactivator, structurally related to the natural substrate androstenedione. It acts as a false substrate for the aromatase enzyme, and is processed to an intermediate that binds irreversibly to the active site of the enzyme, causing its inactivation, an effect also known as “suicide inhibition.” Exemestane significantly lowers circulating estrogen concentrations in postmenopausal women, but has no detectable effect on adrenal biosynthesis of corticosteroids or aldosterone. Exemestane has no effect on other enzymes involved in the steroid pathway up to a concentration at least 600 times higher than that inhibiting the aromatase enzyme.

12.2 Pharmacodynamics
Effect on Estrogens: Multiple doses of exemestane ranging from 0.5 to 600 mg/day were administered to postmenopausal women with advanced breast cancer. Plasma estrogen (estradiol, estrone, and estrone sulfate) suppression was seen starting at a 5-mg daily dose of exemestane, with a maximum suppression of at least 85% to 95% achieved at a 25-mg dose. Exemestane 25 mg daily reduced whole body aromatization (as measured by injecting radiolabeled androstenedione) by 98% in postmenopausal women with advanced breast cancer. A single dose of exemestane of 2.5 mg lowered the estradiol concentration of circulating estrogens occurred 2 to 3 days after dosing and persisted for 4 to 5 days.

Effect on Corticosteroids: In multiple-dose trials of doses up to 200 mg daily, exemestane selectivity was assessed by examining its effect on adrenal steroids. Exemestane did not affect cortisol or aldosterone secretion at baseline or in response to ACTH at any dose. Thus, no glucocorticoid or mineralocorticoid replacement therapy is necessary with exemestane treatment.

Other Endocrine Effects: Exemestane does not bind significantly to steroid receptors, except for a slight affinity for the androgen receptor (0.28% relative to dihydrotestosterone). The binding affinity of its 17-dihydrometicalibole for the androgen receptor, however, is 100 times that of the parent compound. Daily doses of exemestane up to 25 mg had no significant effect on circulating levels of androstenedione, dehydroepiandrosterone sulfate, or 17-oxysteroids, and were associated with small decreases in circulating levels of testosterone. Increases in testosterone and androstenedione levels have been observed or 17-hydroxyprogesterone, and were associated with small decreases in circulating levels of testosterone.

12.3 Pharmacokinetics
Following oral administration to healthy postmenopausal women, plasma concentrations of exemestane decline polyexponentially with a mean terminal half-life of about 24 hours. The pharmacokinetics of exemestane are dose proportional after single (10 to 200 mg) or repeated oral dosages (0.5 to 50 mg). Following repeated daily doses of exemestane 25 mg, plasma concentrations of unchanged drug are similar to levels measured after a single dose. Pharmacokinetic parameters in postmenopausal women with advanced breast cancer following single or repeated doses have been compared with those in healthy, postmenopausal women. After repeated dosing, the average oral clearance in women with advanced breast cancer was 54% lower than in healthy postmenopausal women, with a corresponding increase in systemic exposure. Mean AUC values following repeated doses in women with breast cancer (75.4 ng·h/mL) were about twice those in healthy women (41.4 ng·h/mL).

Absorption: Following oral administration, exemestane appeared to be absorbed more rapidly in women with breast cancer than in the healthy women, with a mean t1/2α of 1.2 hours in the women with breast cancer and 2.9 hours in healthy women. Approximately 40% to 70% of administered exemestane was absorbed from the gastrointestinal tract. A high-fat breakfast increased AUC and Cmax of exemestane by 59% and 39%, respectively, compared to fasted state.

Distribution: Exemestane is distributed extensively into tissues. Exemestane is 90% bound to plasma proteins and the fraction bound is independent of the total concentration. Albumin and α1-acid glycoprotein both contribute to the binding. The distribution of exemestane and its metabolites into blood cells is negligible.

Metabolism: Exemestane is extensively metabolized, with levels of the unchanged drug in plasma accounting for less than 10% of the total radioactivity. The initial steps in the metabolism of exemestane are oxidation of the methylene group in position 6 and reduction of the 17-keto group with subsequent formation of many secondary metabolites. Each metabolite accounts only for a limited amount of drug-related material. The metabolites are inactive or inhibit aromatase with decreased potency compared with the parent drug. One metabolite may have androgenic activity [see Clinical Pharmacology (12.2)]. Studies using human liver preparations indicate that cytchrome P 450 3A4 (CYP 3A4) is the principal isoenzyme involved in the oxidation of exemestane. Exemestane is metabolized also by aldoketo reductases.

Elimination: Following administration of radiolabeled exemestane to healthy postmenopausal women, the cumulative amounts of radioactivity excreted in urine and feces were similar (42 ± 3% in urine and 42 ± 6% in feces over a 1-week collection period). The amount of drug excreted unchanged in urine was less than 1% of the dose.

Specific Populations
Geriatric: Healthy postmenopausal women aged 43 to 68 years were studied in the pharmacokinetics of exemestane. Age-related alterations in exemestane pharmacokinetics were not seen over this age range.

Gender: The pharmacokinetics of exemestane following administration of a single, 25-mg tablet to fasted healthy males (mean age 32 years) were similar to the pharmacokinetics of exemestane in fasted healthy postmenopausal women (mean age 55 years).

Race: The influence of race on exemestane pharmacokinetics has not been evaluated.

Hepatic Impairment: The pharmacokinetics of exemestane have been investigated in subjects with moderate or severe hepatic impairment (Childs-Pugh B or C). Following a single 25-mg oral dose, the AUC of exemestane was approximately 3 times higher than that observed in healthy volunteers.

Renal Impairment: The AUC of exemestane after a single 25-mg dose was approximately 3 times higher in subjects with moderate or severe renal insufficiency (creatinine clearance <35 mL/min/1.73 m²) compared with the AUC in healthy volunteers.

Pediatric: The pharmacokinetics of exemestane have not been studied in pediatric patients.

Drug Interactions
Exemestane does not inhibit any of the major CYP isoenzymes, including CYP 1A2, 2C9, 2D6, 2E1, and 3A4.

In a pharmacokinetic interaction study of 10 healthy postmenopausal volunteers pretreated with low-dose CYP 3A4 inducer rifampicin 600 mg daily for 14 days followed by a single dose of exemestane 25 mg, the mean plasma Cmax and AUC of exemestane were decreased by 41% and 54%, respectively [see Dosing and Administration (2.2) and Drug Interactions (7)].

In a clinical pharmacokinetic study, coadministration of ketoconazole, a potent inhibitor of CYP 3A4, has no significant effect on exemestane pharmacokinetics. Although no meaningful drug-drug interaction studies with inhibitors have been conducted, significant effects on exemestane clearance by CYP isoenzyme inhibitors appear unlikely.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
A 2-year carcinogenicity study in mice at doses of 50, 150, and 450 mg/kg/day exemestane (gavage), resulted in an increased incidence of hepatocellular adenomas and/or carcinomas in both genders at the high dose level. Plasma AUC 0–24 h/mL of the high dose were 2575 ± 386 and 5667 ±1833 ng·hr/mL in males and females (approx. 34 and 75 fold the AUC in postmenopausal women). An increased incidence of females, but not males, of mammary tumors was observed in male at the high dose of 450 mg/kg/day. Since the doses tested in mice did not achieve an MTD, neoplastic findings in organs other than liver and kidneys remain unknown.

A separate carcinogenicity study was conducted in rats at the doses of 30, 100, and 315 mg/kg/day exemestane (gavage) for 92 weeks in males and 2 years in females. No evidence of carcinogenic activity up to the highest dose tested of 315 mg/kg/day was observed. Several females (20%), but no males, of major organ tumors was observed in male at the high dose of 450 mg/kg/day. Since the doses tested in mice did not achieve an MTD, neoplastic findings in organs other than liver and kidneys remain unknown.

A separate carcinogenicity study was conducted in rats at the doses of 30, 100, and 315 mg/kg/day exemestane (gavage) for 92 weeks in males and 2 years in females. No evidence of carcinogenic activity up to the highest dose tested of 315 mg/kg/day was observed. Several females (20%), but no males, of major organ tumors was observed in male at the high dose of 450 mg/kg/day. Since the doses tested in mice did not achieve an MTD, neoplastic findings in organs other than liver and kidneys remain unknown.

In a pharmacokinetically interaction study with low-dose CYP 3A4 inducer rifampicin 600 mg daily for 14 days followed by a single dose of exemestane 25 mg, the mean plasma Cmax and AUC of exemestane were decreased by 41% and 54%, respectively [see Dosing and Administration (2.2) and Drug Interactions (7)].

In a clinical pharmacokinetic study, coadministration of ketoconazole, a potent inhibitor of CYP 3A4, has no significant effect on exemestane pharmacokinetics. Although no meaningful drug-drug interaction studies with inhibitors have been conducted, significant effects on exemestane clearance by CYP isoenzyme inhibitors appear unlikely.

14 CLINICAL STUDIES
14.1 Adjuvant Treatment in Early Breast Cancer
The Intergroup Exemestane Study 031 (IES) was a randomized, double-blind, multi-center, multinational study comparing exemestane (25 mg/day) vs. tamoxifen (20 or 30 mg/day) in postmenopausal women with early breast cancer. Patients who remained...
The primary objective of the study was to determine whether, in terms of disease-free survival, it was more effective to switch to AROMASIN rather than continuing tamoxifen therapy for the remainder of five years. Disease-free survival was defined as the time from randomization to time of local or distant recurrence of breast cancer, contralateral invasive breast cancer, or death from any cause.

The secondary objectives were to compare the two regimens in terms of overall survival and long-term tolerability. Time to contralateral invasive breast cancer and distant recurrence-free survival were also evaluated.

A total of 4724 patients in the intent-to-treat (ITT) analysis were randomized to AROMASIN (exemestane tablets) 25 mg once daily (N = 2352) or to continue to receive tamoxifen once daily at the same dose received before randomization (N = 2372). Demographics and baseline tumor characteristics are presented in Table 5. Prior breast cancer therapy is summarized in Table 6.
14.2 Treatment of Advanced Breast Cancer

Exemestane 25 mg administered once daily was evaluated in a randomized double-blind, multicenter, multinational comparative study and in two multicenter single-arm studies of postmenopausal women with advanced breast cancer who had disease progression after treatment with tamoxifen for metastatic disease or as adjuvant therapy. Some patients also have received prior cytotoxic therapy, either as adjuvant treatment or for metastatic disease.

The primary purpose of the three studies was evaluation of objective response rate (complete response [CR] and partial response [PR]). Time to tumor progression and overall survival were also assessed in the comparative trial. Response rates were assessed based on World Health Organization (WHO) criteria, and in the comparative study, were submitted to an external review committee that was blinded to patient treatment. In the comparative study, 769 patients were randomized to receive AROMASIN (exemestane tablets) 25 mg once daily (N = 366) or megestrol acetate 40 mg four times daily (N = 403). Demographics and baseline characteristics are presented in Table 9.

Table 9. Demographics and Baseline Characteristics from the Comparative Study of Postmenopausal Women with Advanced Breast Cancer Whose Disease Had Progressed after Tamoxifen Therapy

<table>
<thead>
<tr>
<th>Parameter</th>
<th>AROMASIN (N = 366)</th>
<th>Megestrol Acetate (N = 403)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (range)</td>
<td>65 (35–89)</td>
<td>65 (30–91)</td>
</tr>
<tr>
<td>ECOG Performance Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>167 (46%)</td>
<td>187 (46%)</td>
</tr>
<tr>
<td>1</td>
<td>162 (44%)</td>
<td>172 (43%)</td>
</tr>
<tr>
<td>2</td>
<td>34 (9%)</td>
<td>42 (10%)</td>
</tr>
<tr>
<td>Receptor Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ER and/or PgR +</td>
<td>246 (67%)</td>
<td>274 (68%)</td>
</tr>
<tr>
<td>ER and PgR unknown</td>
<td>116 (32%)</td>
<td>128 (32%)</td>
</tr>
<tr>
<td>Responders to prior tamoxifen</td>
<td>68 (19%)</td>
<td>85 (21%)</td>
</tr>
<tr>
<td>NE for response to prior tamoxifen</td>
<td>46 (13%)</td>
<td>41 (10%)</td>
</tr>
<tr>
<td>Site of Metastasis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visceral ± other sites</td>
<td>207 (57%)</td>
<td>239 (59%)</td>
</tr>
<tr>
<td>Bone only</td>
<td>61 (17%)</td>
<td>73 (18%)</td>
</tr>
<tr>
<td>Soft tissue only</td>
<td>54 (15%)</td>
<td>51 (13%)</td>
</tr>
<tr>
<td>Bone &amp; soft tissue</td>
<td>43 (12%)</td>
<td>38 (9%)</td>
</tr>
<tr>
<td>Measurable Disease</td>
<td>287 (78%)</td>
<td>314 (78%)</td>
</tr>
<tr>
<td>Prior Tamoxifen Therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjuvant or Neoadjuvant</td>
<td>145 (40%)</td>
<td>152 (38%)</td>
</tr>
<tr>
<td>Advanced Disease, Outcome</td>
<td>179 (49%)</td>
<td>210 (52%)</td>
</tr>
<tr>
<td>CR, PR, or SD ≥ 6 months</td>
<td>42 (12%)</td>
<td>41 (10%)</td>
</tr>
<tr>
<td>SD &lt; 6 months, PD or NE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior Chemotherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For advanced disease ± adjuvant</td>
<td>58 (16%)</td>
<td>67 (17%)</td>
</tr>
<tr>
<td>Adjuvant only</td>
<td>104 (28%)</td>
<td>108 (27%)</td>
</tr>
<tr>
<td>No chemotherapy</td>
<td>203 (56%)</td>
<td>226 (56%)</td>
</tr>
</tbody>
</table>

The efficacy results from the comparative study are shown in Table 10. The objective response rates observed in the two treatment arms showed that AROMASIN was not different from megestrol acetate. Response rates for AROMASIN from the two single-arm trials were 23.4% and 28.1%.
What is AROMASIN?
AROMASIN is used in women who are past menopause. It is used in:

- **Early breast cancer** (cancer that has not spread outside the breast). AROMASIN lowers the risk the cancer will come back. It is for women who:
  - Have cancer that needs the female hormone estrogen to grow
  - Had surgery for breast cancer, and possibly other treatments for breast cancer including radiation or chemotherapy and
  - Have taken tamoxifen for 2 to 3 years and
  - Are switching to AROMASIN to finish 5 years in a row of hormonal therapy.

- **Advanced breast cancer** (cancer that has spread), to treat cancer that came back after treatment with tamoxifen.

Certain breast cancers need the female hormone estrogen to grow (estrogen receptor-positive cancer).

While you are taking AROMASIN, your body stops making estrogen. AROMASIN may slow or stop the growth of the cancer.

AROMASIN is hormone therapy. It is not chemotherapy. It is not hormone replacement therapy (HRT).

Who should not take AROMASIN?
Do not take AROMASIN if:

- You are allergic to AROMASIN or anything in it. The active ingredient is exemestane. There is a list of what is in AROMASIN at the end of this leaflet.

What should I tell my doctor before taking AROMASIN?
Tell your doctor about all your medical conditions. Be sure to tell your doctor if you:

- Are still having menstrual periods (are not past menopause). AROMASIN is only for women who are past menopause.
- Are pregnant or could be pregnant. Taking AROMASIN during pregnancy may cause birth defects or miscarriage.
- Are breast-feeding. Do not breast-feed while you are being treated with AROMASIN.
- Have liver or kidney problems.

Tell your doctor about all the medicines you take. Include prescription and nonprescription medicines, herbal remedies, and vitamins. AROMASIN and other medicines may affect how each other work. Be sure to tell your doctor if you take:

- Medicines with estrogen, such as Premarin®, other hormone replacement therapy, or birth control pills or patches. AROMASIN should not be taken with these medicines as they could affect how well AROMASIN works.
- Rifadin® (rifampin)
- Dilantin® (phenytoin), Tegretol® (carbamazepine), or Luminal® (phenobarbital)
- St. John’s wort

Know what medicines you take. Keep a list of them with you. Show it to your doctor or pharmacist each time you get a new prescription.

What are the possible side effects of AROMASIN?

**Serious Side Effects**
- Bone loss. AROMASIN may reduce your bone mineral density (BMD) over time. This may raise your risk for bone fractures.
- Chest pain, heart failure, or stroke. A small number of women had chest pain, heart failure, or a stroke while taking AROMASIN.

**Common Side Effects**
- hot flashes • feeling tired • joint pain
- headache • trouble sleeping • increased sweating
- depression • feeling anxious • upset stomach
- difficulty in breathing

Your doctor may do blood tests to check your liver and kidney function during treatment.

These are not all the side effects with AROMASIN. Ask your cancer nurse or doctor for a more complete list.

How should I take AROMASIN?

- Take your dose of AROMASIN once a day, every day, after a meal. AROMASIN comes in 25mg tablets you take by mouth. Your doctor will tell you how many AROMASIN tablets to take for your dose.
- Try to take your treatment at the same time each day.
- Take your medicine for as long as your doctor tells you.
- Tell your doctor if you do not feel well after starting AROMASIN.
- If you miss a dose of AROMASIN, take it as soon as you remember. If it is close to your next dose, just take your next dose at your regular time.
- Don’t take more than one dose of AROMASIN at a time.
- Make a note of when your prescription will run out. That way, you can get it refilled on time.

How should I store AROMASIN?

- Keep AROMASIN and all medicines out of the reach of children.
- Store AROMASIN at room temperature, 77°F (25°C), in its original container.

General information about AROMASIN

Doctors can prescribe medicines for conditions that are not in the patient information leaflet. Use AROMASIN only for what your doctor prescribed. Do not give it to other people, even if they have the same conditions you have. It may harm them.

This leaflet gives the most important information about AROMASIN. For more information about AROMASIN, talk with your doctor, nurse, or pharmacist. You can visit our Web site at www.AROMASIN.com, or call 1-888-AROMASIN (1-888-276-6274).

What is in AROMASIN?

**Active ingredient:** exemestane

**Inactive ingredients:** mannitol, crospovidone, polysorbate 80, hypro-mellose, colloidal silicon dioxide, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, simethicone, polyethylene glycol 6000, sucrose, magnesium carbonate, titanium dioxide, methylparaben, and polyvinyl alcohol.

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