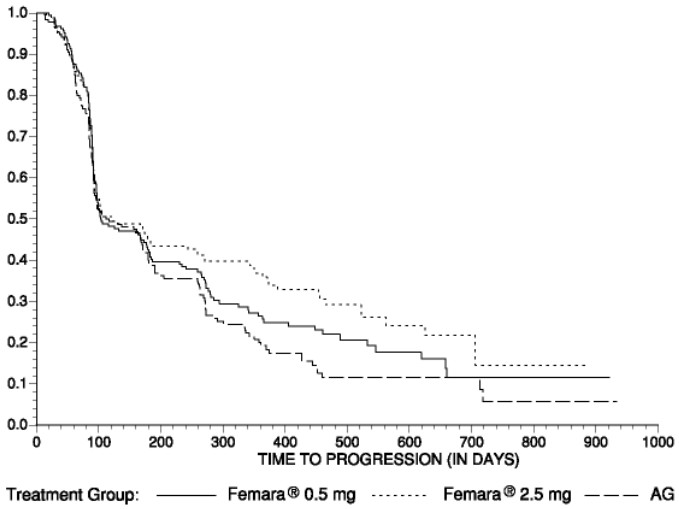
The Kaplan-Meier curves for progression for the aminoglutethimide study is shown in Figure 5.

Figure 5: Kaplan-Meier Estimates of Time to Progression (Aminoglutethimide Study)



16 HOW SUPPLIED/STORAGE AND HANDLING

Packaged in HDPE bottles with a safety screw cap.

2.5 mg tablets

Bottles of 30 tablets.....NDC 0078-0249-15

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Embryo-Fetal Toxicity

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during Femara therapy and for at least 3 weeks after the last dose. Advise females to contact their healthcare provider if they become pregnant, or if pregnancy is suspected, during treatment with Femara *[see Warnings and Precautions (5.6) and Use in Specific Populations (8.1, 8.3)]*.

Lactation

Advise women not to breastfeed during Femara treatment and for at least 3 weeks after the last dose *[see Use in Specific Populations (8.2)]*.

Infertility

Advise females and males of reproductive potential of the potential for reduced fertility from Femara *[see Use in Specific Populations (8.3)]*.

Fatigue and Dizziness

Since fatigue and dizziness have been observed with the use of Femara and somnolence was uncommonly reported, caution is advised when driving or using machinery.

Bone Effects

Consideration should be given to monitoring bone mineral density.

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