



VERZENIO™ (abemaciclib) Tablets, for oral use

USPI March 2023
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1 INDICATIONS AND USAGE

1.1 Early Breast Cancer

VERZENIO™ (abemaciclib) is indicated:

- in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence (see Clinical Studies (12.1)).

1.2 Advanced or Metastatic Breast Cancer

VERZENIO™ (abemaciclib) is indicated:

- in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose and Schedule

- When used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, the recommended dose of VERZENIO is 150 mg taken orally twice daily. Refer to the Full Prescribing Information for the recommended dose of the fulvestrant, tamoxifen, or aromatase inhibitor being used.
- In postmenopausal women treated with the combination of VERZENIO plus an aromatase inhibitor should be treated with a gonadotropin-releasing hormone agonist (GnRH) according to current clinical practice standards.
- In premenopausal women treated with the combination of VERZENIO plus fulvestrant should be treated with a GnRH according to current clinical practice standards.
- When used as monotherapy, the recommended dose of VERZENIO is 200 mg taken orally twice daily.
- For early breast cancer, continue VERZENIO until completion of 2 years of treatment or until disease recurrence, or unacceptable toxicity.
- For advanced or metastatic breast cancer, continue treatment until disease progression or unacceptable toxicity.

VERZENIO may be taken with or without food (see Clinical Pharmacology (12.3)).

Instruct patients to take their doses of VERZENIO at approximately the same times every day.

If the patient vomits or misses a dose of VERZENIO, instruct the patient to take the next dose at the scheduled time. Do not instruct patients to swallow VERZENIO tablets whole and not to chew, crush, or split tablets before swallowing. Instruct patients not to ingest VERZENIO tablets if broken, cracked, or otherwise not intact.

2.2 Dose Modification

Dose Modifications for Adverse Reactions

The recommended VERZENIO dose modifications for adverse reactions are provided in Tables 1-7. Discontinue VERZENIO for patients unable to tolerate 50 mg twice daily.

Table 1: VERZENIO Dose Modification – Adverse Reactions		
Dose Level	VERZENIO Dose Combination with Fulvestrant, tamoxifen, or an aromatase inhibitor	VERZENIO Dose for Monotherapy
Recommended starting dose	150 mg twice daily	200 mg twice daily
First dose reduction	100 mg twice daily	150 mg twice daily
Second dose reduction	50 mg twice daily	100 mg twice daily
Third dose reduction	not applicable	50 mg twice daily

Table 2: VERZENIO Dose Modification and Management – Hematologic Toxicities^a

Monitor complete blood counts prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated.

CTCAE Grade	VERZENIO Dose Modifications
Grade 1 or 2	No dose modification is required.
Grade 3	Suspend dose until toxicity resolves to baseline or Grade 2. Dose reduction is not required.
Grade 3 recurrent, or Grade 4	Suspend dose until toxicity resolves to baseline or Grade 2. Resume at next lower dose.

Abbreviation: CTCAE = Common Terminology Criteria for Adverse Events.
a. If blood growth factors (neutrophils, platelets, and hemoglobin) are decreased at least 48 hours after the last dose of blood cell growth factor and until toxicity resolves to Grade 2. Resume at next lower dose unless already performed for the toxicity that led to the use of the growth factor. Growth factor support should be discontinued once toxicity resolves.

Table 3: VERZENIO Dose Modification and Management – Diarrhea

At the first sign of loose stools, start treatment with antidiarrheal agents and increase intake of oral fluids.

CTCAE Grade	VERZENIO Dose Modifications
Grade 1	No dose modification is required.
Grade 2	If toxicity does not resolve within 24 hours to Grade 1, suspend dose until resolution. No dose reduction is required.
Grade 2 that persists or recurs after resuming the same dose despite maximal supportive measures	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Grade 3 or 4 or requires hospitalization	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.

Table 4: VERZENIO Dose Modification and Management – Hepatotoxicity

Monitor ALT, AST, and serum bilirubin prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated.

CTCAE Grade for ALT and AST	VERZENIO Dose Modifications
Grade 1 (>1.5-3.0 x ULN)	No dose modification is required.
Grade 2 (>3.0-5.0 x ULN) WITHOUT increase in total bilirubin above 2 x ULN	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Persistent or Recurrent Grade 2, or Grade 3 (>5.0-10.0 x ULN) WITHOUT increase in total bilirubin above 2 x ULN	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Elevation in AST and/or ALT >3 x ULN WITH total bilirubin >2 x ULN, in the absence of cholestasis	Discontinue VERZENIO.
Grade 4 (>20.0 x ULN)	Discontinue VERZENIO.

Abbreviations: ALT = alanine aminotransferase, AST = aspartate aminotransferase, ULN = upper limit of normal.

Table 5: VERZENIO Dose Modification and Management – Interstitial Lung Disease/Pneumonitis

CTCAE Grade	VERZENIO Dose Modifications
Grade 1 or 2	No dose modification is required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures within 7 days to baseline or Grade 1	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Grade 3 or 4	Discontinue VERZENIO.

Table 6: VERZENIO Dose Modification and Management – Venous Thromboembolic Events (VTEs)

CTCAE Grade	VERZENIO Dose Modifications
Any Grade	Suspend dose and treat as clinically indicated. Resume VERZENIO when the patient is clinically stable.

Advanced or Metastatic Breast Cancer

Grade 1 or 2	No dose modification is required.
Grade 3 or 4	Suspend dose until toxicity resolves to baseline or Grade 2. Resume at next lower dose.

Table 7: VERZENIO Dose Modification and Management – Other Toxicities^a

CTCAE Grade	VERZENIO Dose Modifications
Grade 1 or 2	No dose modification is required.
Persistent or recurrent Grade 2 toxicity that does not resolve with maximal supportive measures within 7 days to baseline or Grade 1	Suspend dose until toxicity resolves to baseline or Grade 1. Resume at next lower dose.
Grade 3 or 4	Suspend dose until toxicity resolves to baseline or Grade 2. Resume at next lower dose.

^a Excluding diarrhea, hematologic toxicity, hepatotoxicity, ILD/pneumonitis, and VTEs. Refer to the Full Prescribing Information for coadministered fulvestrant, tamoxifen, or an aromatase inhibitor for dose modifications and other relevant safety information.

Dose Modification for Use with Strong and Moderate CYP3A Inhibitors
Avoid concomitant use of the strong CYP3A inhibitors ketoconazole, in patients with concomitant use of strong CYP3A inhibitors other than ketoconazole, in patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the VERZENIO dose to 100 mg twice daily. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the VERZENIO dose to 50 mg twice daily. If a patient taking VERZENIO discontinues a CYP3A inhibitor, increase the VERZENIO dose (after 3 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor (see Drug Interactions (7.1) and Clinical Pharmacology (12.3)).

With concomitant use of moderate CYP3A inhibitors, monitor for adverse reactions and consider reducing the VERZENIO dose in 50 mg decrements as demonstrated in Table 1, if necessary.

Dose Modification for Patients with Severe Hepatic Impairment
For patients with severe hepatic impairment (Child Pugh-C), reduce the VERZENIO dosing frequency to once daily (see Use in Specific Populations (8.7) and Clinical Pharmacology (12.3)).

Refer to the Full Prescribing Information for the coadministered fulvestrant, tamoxifen, or aromatase inhibitor for dose modification requirements for severe hepatic impairment.

3 DOSAGE FORMS AND STRENGTHS

50 mg tablets: modified oval beige tablet with “Lilly” debossed on one side and “50” on the other side.

100 mg tablets: modified oval white to practically white tablet with “Lilly” debossed on one side and “100” on the other side.

150 mg tablets: modified oval yellow tablet with “Lilly” debossed on one side and “150” on the other side.

200 mg tablets: modified oval beige tablet with “Lilly” debossed on one side and “200” on the other side.

Not all pack sizes, strengths or presentation may be registered or marketed.

4 CONTRAINDICATIONS

5.1 Diarrhea

Severe diarrhea associated with dehydration and infection occurred in patients treated with VERZENIO.

Across four clinical trials in 3691 patients, diarrhea occurred in 81% to 90% of patients who received VERZENIO. Grade 3 diarrhea occurred in 8% to 20% of patients receiving VERZENIO (see Adverse Reactions (6.1)).

Most patients experienced diarrhea during the first month of VERZENIO treatment. The median time to onset of the first diarrhea event ranged from 6 to 8 days, and the median duration of Grade 2 and Grade 3 diarrhea ranged from 6 to 11 days and 5 to 8 days, respectively. Across trials, 19% to 20% of patients with diarrhea required a VERZENIO dose interruption and 13% to 23% required a dose reduction.

Instruct patients to start antidiarrheal therapy such as loperamide at the first sign of loose stools, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow up (see Patient Counseling Information (17)).

For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue VERZENIO until toxicity resolves to Grade 1, and then resume VERZENIO at the next lower dose (see Dosage and Administration (2.2)).

5.2 Neutropenia

Neutropenia, including febrile neutropenia and fatal neutropenic sepsis, occurred in patients treated with VERZENIO.

Across four clinical trials in 3691 patients, neutropenia occurred in a 37% to 40% of patients receiving VERZENIO. A Grade ≥3 decrease in neutrophil count (based on laboratory findings) occurred in 19% to 32% of patients receiving VERZENIO. Across trials, the median time to the first episode of Grade ≥3 neutropenia ranged from 29 days to 33 days, and the median duration of Grade ≥3 neutropenia ranged from 11 days to 16 days (see Adverse Reactions (6.1)).

Febrile neutropenia has been reported in <1% of patients exposed to VERZENIO across trials. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider (see Patient Counseling Information (17)).

Monitor complete blood counts prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia (see Dosage and Administration (2.2)).

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Severe, life-threatening, or fatal interstitial lung disease (ILD) or pneumonitis can occur in patients treated with VERZENIO and other CDK4/6 inhibitors. In VERZENIO-treated patients in early breast cancer (monarchC, N=2791), 3% of patients experienced ILD or pneumonitis of any grade. 0.4% were Grade 3 or 4 and there was one fatality (0.1%). In VERZENIO-treated patients in advanced or metastatic breast cancer (N=900) (MONARCH 1, MONARCH 2, MONARCH 3), 3.3% of VERZENIO-treated patients had ILD or pneumonitis of any grade. 0.6% had Grade 3 or 4, and 0.4% had fatal outcomes. Additional cases of ILD or pneumonitis have been observed in the postmarketing setting, with fatalities reported (see Adverse Reactions (6.2)).

Monitor patients for pulmonary symptoms indicative of ILD or pneumonitis. Symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded by means of appropriate investigations.

Dose interruption or dose reduction is recommended for patients who develop persistent or recurrent Grade 2 ILD or pneumonitis. Permanently discontinue VERZENIO in all patients with Grade 3 or 4 ILD or pneumonitis (see Dosage and Administration (2.2)).

5.4 Hepatotoxicity

Grade ≥3 ALT (2% to 6%) and AST (2% to 3%) were reported in patients receiving VERZENIO.

Across three clinical trials in 3559 patients (monarchC, MONARCH 2, MONARCH 3), the rates observed in Grade ≥3 ALT increases ranged from 57 to 67 days and the median time to resolution to Grade ≥3 was 13 to 14 days. The median time to onset of Grade ≥3 ALT increases ranged from 71 to 185 days and the median time to resolution to Grade <3 ranged from 11 to 15 days.

Monitor liver function tests (LFTs) prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, dose discontinuation, or delay in starting treatment cycles is recommended for patients who develop persistent or recurrent Grade 2, or any Grade 3 or Grade 4 hepatic transaminase elevation (see Dosage and Administration (2.2)).

5.5 Venous Thromboembolism

Across three clinical trials in 3559 patients (monarchC, MONARCH 2, MONARCH 3), venous thromboembolic events were reported in 2% to 5% of patients treated with VERZENIO. Venous thromboembolic events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. In clinical trials, deaths due to venous thromboembolism have been reported in patients treated with VERZENIO.

VERZENIO has not been studied in patients with early breast cancer who had a history of venous thromboembolism.

Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate. Dose interruption is recommended for early breast cancer patients with any grade venous thromboembolic event and for advanced or metastatic breast cancer patients with a Grade 3 or 4 venous thromboembolic event (see Dosage and Administration (2.2)).

5.6 Embryo-Fetal Toxicity

Based on findings from animal studies and the mechanism of action, VERZENIO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of abemaciclib to pregnant rats during the period of organogenesis caused teratogenicity and embryonic loss at >20% maternal exposures that were similar to the human clinical exposure based on area under the curve (AUC) at the maximum recommended human dose.

Advise pregnant women of the potential for adverse effects on the fetus. Advise females of reproductive potential to use effective contraception during treatment with VERZENIO for 3 weeks after the last dose (see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.3)).

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Diarrhea (see Warnings and Precautions (5.1)).
- Interstitial Lung Disease (ILD) or Pneumonitis (see Warnings and Precautions (5.3)).
- Precautions (5.3).
- Warnings and Precautions (5.4).
- Venous Thromboembolism (see Warnings and Precautions (5.5)).

6.1 Clinical Studies 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 practice.

The safety population described in the Warnings and Precautions reflect exposure to VERZENIO in 3691 patients from four clinical trials in combination with fulvestrant, MONARCH 2, and MONARCH 3. The safety population includes exposure to VERZENIO as a single agent at 200 mg twice daily in 152 patients in MONARCH 1 and to VERZENIO at 150 mg twice daily in 3691 patients administered in combination with fulvestrant, tamoxifen, or an aromatase inhibitor in monarchC, MONARCH 2, and MONARCH 3. The median duration of exposure ranged from 4.5 months in MONARCH 1 to 24 months in MONARCH 3.

The most common adverse reactions (≥10% of patients) in combination with fulvestrant were: diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia.

monarchC, VERZENIO in Combination with Tamoxifen or an Aromatase Inhibitor as Adjuvant Treatment
Adult patients with HR-positive, HER2-negative, node-positive early breast cancer at a high risk of recurrence.

The safety of VERZENIO was evaluated in monarchC, a study of 5591 adult patients receiving VERZENIO plus endocrine therapy (tamoxifen or an aromatase inhibitor) or endocrine therapy (tamoxifen or an aromatase inhibitor) alone (see Clinical Studies (14.1)). Patients were randomly assigned to receive 150 mg of VERZENIO orally, twice daily, plus tamoxifen or an aromatase inhibitor, or tamoxifen or an aromatase inhibitor, for two years or until discontinuation criteria were met. The median duration of VERZENIO treatment was 24 months.

The most frequently reported (>5%) Grade 3 or 4 adverse reactions were neutropenia, leukopenia, diarrhea, and lymphopenia.

Fatal adverse reactions occurred in 0.8% of patients who received VERZENIO plus endocrine therapy (tamoxifen or an aromatase inhibitor), including: cardiac failure (0.1%), cardiac arrest, myocardial infarction, ventricular fibrillation, cerebral hemorrhage, cerebrovascular accident, pneumonitis, hypoxia, diarrhea, and mesenteric artery thrombosis (0.03% each).

Permanent VERZENIO treatment discontinuation due to an adverse reaction was reported in 19% of patients receiving VERZENIO, plus tamoxifen or an aromatase inhibitor. Of the patients receiving tamoxifen or an aromatase inhibitor, 1% permanently discontinued due to an adverse reaction. The most common adverse reactions leading to VERZENIO discontinuations were diarrhea (0.4%), fatigue (0.2%), and neutropenia (0.9%).

Dose interruptions in VERZENIO plus endocrine therapy occurred in 62% of patients receiving VERZENIO plus tamoxifen or an aromatase inhibitor. Adverse reactions leading to VERZENIO dose interruptions in >5% of patients were diarrhea (20%), neutropenia (19%), leukopenia (7%), and fatigue (6%).

Dose reductions of VERZENIO due to an adverse reaction occurred in 44% of patients receiving VERZENIO plus endocrine therapy (tamoxifen or an aromatase inhibitor). Adverse reactions leading to VERZENIO dose reductions in >5% were diarrhea (17%), neutropenia (8%), and fatigue (6%).

The most common adverse reactions reported (>20%) in the VERZENIO, plus tamoxifen or an aromatase inhibitor, arm and >2% higher than the tamoxifen or an aromatase inhibitor arm were: diarrhea, infections, neutropenia, leukopenia, nausea, anemia, and headache. Adverse reactions are shown in Table 8 and laboratory abnormalities are shown in Table 9.

Table 8: Adverse Reactions (≥10% of Patients Receiving VERZENIO Plus Tamoxifen or an Aromatase Inhibitor (with a Difference Between Arms of >2%) in monarchC

VERZENIO Plus Tamoxifen or an Aromatase Inhibitor N=2791							Tamoxifen or an Aromatase Inhibitor N=2800						
All Grades ^a	Grade 3 ^b	Grade 4 ^b	All Grades ^a	Grade 3 ^b	Grade 4 ^b		All Grades ^a	Grade 3 ^b	Grade 4 ^b				
Diarrhea	84	8	0	9	0.2	0							
Nausea	30	0.5	0	9	<0.1	0							
Vomiting	18	0.5	0	4.6	0.1	0							
Stomatitis ^c	14	0.1	0	5	0	0							

Table 9: Laboratory Abnormalities (≥10% of Patients Receiving VERZENIO Plus Tamoxifen or an Aromatase Inhibitor (with a Difference Between Arms of >2%) in monarchC

VERZENIO Plus Tamoxifen or an Aromatase Inhibitor N=2791							Tamoxifen or an Aromatase Inhibitor N=2800						
All Grades ^a	Grade 3 ^b	Grade 4 ^b	All Grades ^a	Grade 3 ^b	Grade 4 ^b		All Grades ^a	Grade 3 ^b	Grade 4 ^b				
Neutrophil count decreased	84	18	0.7	23	1.6	0.3							
Anemia	68	10	0	17	0.1	0.1							
Lymphocyte count decreased	59	13	0.2	24	2.4	0.1							
Platelet count decreased	37	0.7	0.2	10	0.1	0.1							
Alanine aminotransferase increased	37	2.5	<0.1	24	1.2	0							
Aspartate aminotransferase increased	31	1.5	<0.1	18	0.9	0							
Hypokalemia	11	1.2	0.1	3.8	0.1	0.1							

^a Includes diarrhea, hematologic toxicity, hepatotoxicity, ILD/pneumonitis, and VTEs. Refer to the Full Prescribing Information for coadministered fulvestrant, tamoxifen, or an aromatase inhibitor for dose modifications and other relevant safety information.

Dose Modification for Use with Strong and Moderate CYP3A Inhibitors
Avoid concomitant use of the strong CYP3A inhibitors ketoconazole, in patients with concomitant use of strong CYP3A inhibitors other than ketoconazole, in patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the VERZENIO dose to 100 mg twice daily. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the VERZENIO dose to 50 mg twice daily. If a patient taking VERZENIO discontinues a CYP3A inhibitor, increase the VERZENIO dose (after 3 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor (see Drug Interactions (7.1) and Clinical Pharmacology (12.3)).

With concomitant use of moderate CYP3A inhibitors, monitor for adverse reactions and consider reducing the VERZENIO dose in 50 mg decrements as demonstrated in Table 1, if necessary.

Dose Modification for Patients with Severe Hepatic Impairment
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Most patients experienced diarrhea during the first month of VERZENIO treatment. The median time to onset of the first diarrhea event ranged from 6 to 8 days, and the median duration of Grade 2 and Grade 3 diarrhea ranged from 6 to 11 days and 5 to 8 days, respectively. Across trials, 19% to 20% of patients with diarrhea required a VERZENIO dose interruption and 13% to 23% required a dose reduction.

Instruct patients to start antidiarrheal therapy such as loperamide at the first sign of loose stools, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow up (see Patient Counseling Information (17)).

For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue VERZENIO until toxicity resolves to Grade 1, and then resume VERZENIO at the next lower dose (see Dosage and Administration (2.2)).

5.2 Neutropenia

Neutropenia, including febrile neutropenia and fatal neutropenic sepsis, occurred in patients treated with VERZENIO.

Across four clinical trials in 3691 patients, neutropenia occurred in a 37% to 40% of patients receiving VERZENIO. A Grade ≥3 decrease in neutrophil count (based on laboratory findings) occurred in 19% to 32% of patients receiving VERZENIO. Across trials, the median time to the first episode of Grade ≥3 neutropenia ranged from 29 days to 33 days, and the median duration of Grade ≥3 neutropenia ranged from 11 days to 16 days (see Adverse Reactions (6.1)).

Febrile neutropenia has been reported in <1% of patients exposed to VERZENIO across trials. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider (see Patient Counseling Information (17)).

Monitor complete blood counts prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia (see Dosage and Administration (2.2)).

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Permanent treatment discontinuation due to an adverse reaction was reported in 13% of patients receiving VERZENIO plus an aromatase inhibitor and in 3% of patients receiving placebo plus an aromatase inhibitor. Adverse reactions leading to permanent discontinuation for patients receiving VERZENIO plus an aromatase inhibitor were diarrhea (2%), ALT increased (2%), infection (1%), venous thromboembolic events (VTE) (1%), neutropenia (0.9%), renal impairment (0.9%), AST increased (0.6%), dyspnea (

