Dosing Guide

everyday Verzenio® abemaciclib
50 | 100 | 150 | 200 mg tablets
twice a day

INDICATION

VERZENIO® (abemaciclib) is a kinase inhibitor indicated[1]:

- 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.
- 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.
- In combination with fulvestrant 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 and prior chemotherapy in the metastatic setting.

IMPORTANT SAFETY INFORMATION FOR VERZENIO® (abemaciclib)

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. 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 26% 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. 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.

Neutropenia, including febrile neutropenia and fatal neutropenic sepsis, occurred in patients treated with Verzenio. Across four clinical trials in 3691 patients, neutropenia occurred in 37 to 46% 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 first episode of Grade ≥3 neutropenia ranged from 29 to 33 days, and the median duration of Grade ≥3 neutropenia ranged from 11 to 16 days. 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.

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.

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 EBC (monarchE), 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 MBC (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.

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 in 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.

Grade ≥3 increases in alanine aminotransferase (ALT) (2 to 6%) and **aspartate aminotransferase (AST)** (2 to 3%) were reported in patients receiving Verzenio. Across three clinical trials in 3559 patients (monarchE, MONARCH 2, MONARCH 3), the median time to onset of Grade ≥3 ALT increases ranged from 57 to 87 days and the median time to resolution to Grade <3 was 13 to 14 days. The median time to onset of Grade ≥3 AST 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 4 hepatic transaminase elevation.

Venous thromboembolic events (VTE) were reported in 2 to 5% of patients across three clinical trials in 3559 patients treated with Verzenio (monarchE, MONARCH 2, MONARCH 3). VTE 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 VTE have been reported in patients treated with Verzenio.

Verzenio has not been studied in patients with early breast cancer who had a history of VTE. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate. Dose interruption is recommended for EBC patients with any grade VTE and for MBC patients with a Grade 3 or 4 VTE.

Verzenio can cause **fetal harm** when administered to a pregnant woman, based on findings from animal studies and the mechanism of action. In animal reproduction studies, administration of abemaciclib to pregnant rats during the period of organogenesis caused teratogenicity and decreased fetal weight at 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 risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Verzenio and for 3 weeks after the last dose.

Based on findings in animals, Verzenio may impair fertility in males of reproductive potential. There are no data on the presence of Verzenio in human milk or its effects on the breastfed child or on milk production. Advise lactating women not to breastfeed during Verzenio treatment and for at least 3 weeks after the last dose because of the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, ≥10%) observed in **monarchE for Verzenio plus tamoxifen or an aromatase inhibitor vs tamoxifen or an aromatase inhibitor, with a difference between arms of ≥2%,** were diarrhea (84% vs 9%), infections (51% vs 39%), neutropenia (46% vs 6%), fatigue (41% vs 18%), leukopenia (38% vs 7%), nausea (30% vs 9%), anemia (24% vs 4%), headache (20% vs 15%), vomiting (18% vs 4.6%), stomatitis (14% vs 5%), lymphopenia (14% vs 3%), thrombocytopenia (13% vs 2%), decreased appetite (12% vs 2.4%), ALT increased (12% vs 6%), AST increased (12% vs 5%), dizziness (11% vs 7%), rash (11% vs 4.5%), and alopecia (11% vs 2.7%).

The most frequently reported ≥5% Grade 3 or 4 adverse reaction that occurred in the Verzenio arm vs the tamoxifen or an aromatase inhibitor arm of monarchE were neutropenia (19.6% vs 1%), leukopenia (11% vs <1%), diarrhea (8% vs 0.2%), and lymphopenia (5% vs <1%).

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Lilly

Recommended Dosing

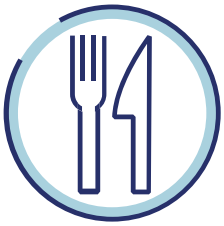
everyday Verzenio abemaciclib
50|100|150|200 mg tablets
twice a day

150 mg in combination with ET[1]* | TWICE DAILY[1]

200 mg single agent[1] | TWICE DAILY[1]

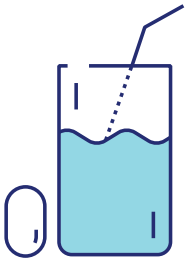
For EBC, continue Verzenio until completion of 2 years of treatment or until disease recurrence or unacceptable toxicity.[1]
For MBC, continue Verzenio until disease progression or unacceptable toxicity.[1]
*Tamoxifen or an AI in EBC and fulvestrant or an AI in MBC. Please refer to the full prescribing information for the recommended dose of the ET selected.

Dosing considerations[1]



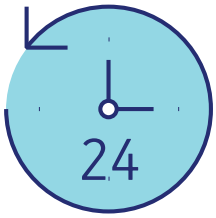
Verzenio has no meal requirements and may be taken with or without food

Patients should avoid grapefruit products when taking Verzenio



Verzenio should be swallowed whole

Patients should not ingest chewed, crushed, or otherwise not intact tablets



Verzenio should be taken at approximately the same times every day

If the patient vomits or misses a dose, they should take the next dose of Verzenio at its scheduled time

The following should receive a gonadotropin-releasing hormone agonist (GnRH) according to current clinical practice standards:[1]

- Pre/perimenopausal women treated with Verzenio plus an AI or fulvestrant
- Men treated with Verzenio plus an AI

Please refer to the full Prescribing Information for additional guidance.

MyRightDose: Dose Exchange Program*

MYRIGHTDOSE

- With MyRightDose, your patient can continue her Verzenio therapy at the appropriate dose for her, without the hassle of delays and at no cost to her
- Shipped to the patient as early as 48 hours after receipt of the enrollment form
- Available at no cost for up to 3 separate dose reductions of between 5 and 28 days of therapy per exchange to any patient prescribed Verzenio for an FDA-approved indication
- Provided by Sonexus™ Health Pharmacy
  Sonexus is a registered trademark of Sonexus Healthcare, LLC

*Additional terms and conditions apply. See the MyRightDose enrollment form for details.

ET=endocrine therapy; EBC=early breast cancer; MBC=metastatic breast cancer; AI=aromatase inhibitor

Recommended Dose Modifications

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Dose Reductions	Verzenio + AI or Fulvestrant	Verzenio (alone)
First Dose Reduction	100 mg BID	150 mg BID
Second Dose Reduction	50 mg BID	100 mg BID
Third Dose Reduction	–	50 mg BID

Color Key
No change in dose
Suspend dose
Reduce dose
Discontinue

Dose modification is recommended based on individual safety and tolerability. Verzenio has been shown to be efficacious at reduced doses. If dose reduction is necessary, reduce the Verzenio dose by 50 mg per dose at a time. Discontinue Verzenio for patients unable to tolerate 50 mg twice daily.[1,2] Refer to the full Prescribing Information for coadminstered fulvestrant, tamoxifen, or an aromatase inhibitor for dose modifications and other relevant safety information.

Diarrhea[1,3,*]	Step 1	Step 2
***At first sign of loose stools, start treatment with antidiarrheal agents, such as loperamide, increase intake of oral fluids and contact your provider. Once an antidiarrheal agent is started, advise patients to follow up if symptoms do not improve after the first 24 hours.**		
CTCAE Grade 1: Increase of <4 stools/day over baseline **CTCAE Grade 2:** Increase of 4-6 stools/day over baseline	No change in dose	
CTCAE Grade 2: Increase of 4-6 stools/day over baseline that does not resolve within 24 hours	Suspend dose until toxicity returns to Grade ≤1	If diarrhea resolves If diarrhea is recurrent or persistent
CTCAE Grade 3: Increase of ≥7 stools/day over baseline **CTCAE Grade 4:** Life-threatening consequences	Suspend dose until toxicity returns to Grade ≤1	Resume at reduced dose

Hematologic Toxicities[1,3,†,*]	Step 1	Step 2
Monitor complete blood counts (CBCs) prior to the start of therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated		
CTCAE Grade 1: Neutropenia (ANC)<LLN-1500/mm^3 **CTCAE Grade 2:** Neutropenia (ANC)<1500-1000/mm^3	No change in dose	
CTCAE Grade 3: Neutropenia (ANC)<1000-500/mm^3	Suspend dose until toxicity returns to Grade ≤2	No change in dose
Recurrent CTCAE Grade 3: Neutropenia (ANC)<1000-500/mm^3 **CTCAE Neutropenia Grade 4:** Neutropenia (ANC)<500/mm^3	Suspend dose until toxicity returns to Grade ≤2	Resume at reduced dose

†If blood cell growth factors are required, suspend Verzenio dose for 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 use as per current treatment guidelines.

*Neutropenia was the most common hematologic toxicity in Verzenio-treated patients

Interstitial Lung Disease/Pneumonitis[1,3]	Step 1	Step 2
CTCAE Grade 1: Asymptomatic **CTCAE Grade 2:** Symptomatic	No change in dose	
Persistant or Recurrent CTCAE Grade 2 that, with maximal support, does not resolve within 7 days to baseline or CTCAE Grade 1	Suspend dose until toxicity resolves to baseline or Grade ≤1	Resume at reduced dose
CTCAE Grade 3: Severe symptoms **CTCAE Grade 4:** Life-threatening	Discontinue abemaciclib	

Hepatoxicity[1,3]	Step 1	Step 2
Monitor liver function tests (LFTs) prior to the start of therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated		
CTCAE Grade 1: ALT/AST>ULN – 3.0 x ULN **CTCAE Grade 2:** ALT/AST>3.0-5.0 x ULN	No change in dose	
Grade 2: Persistant or Recurrent **Grade 3:** ALT/AST>5.0-20.0 x ULN WITHOUT increase in total bilirubin >2 x ULN	Suspend dose until toxicity resolves to baseline or Grade ≤1	Resume at reduced dose
CTCAE Grade 3: With total bilirubin >2 x ULN, in the absence of cholestasis **CTCAE Grade 4:** ALT/AST>20.0 x ULN	Discontinue abemaciclib	

CTCAE=Common Terminology Criteria for Adverse Events; CBCs=complete blood counts; ALT=alanine transaminase; AST=aspartate aminotransferase; LFTs=liver function tests

Recommended Dose Modifications

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Venous Thromboembolic Events (VTEs)[1,3]	Step 1	Step 2
Early Breast Cancer–Any Grade	Suspend dose until patient is clinically stable	No change in dose
Advanced or Metastatic Breast Cancer **CTCAE Grade 1:** Medical intervention not indicated (e.g., superficial thrombosis) **CTCAE Grade 2:** Medical intervention indicated	No change in dose	
Advanced or Metastatic Breast Cancer **CTCAE Grade 3:** Urgent medical intervention indicated (e.g., pulmonary embolism or intracardiac thrombus) **CTCAE Grade 4:** Life-threatening consequences with hemodynamic or neurologic instability	Suspend dose until patient is clinically stable	No change in dose

Other Toxicities[1,3,*]	Step 1	Step 2
CTCAE Grade 1 or 2	No change in dose	
CTCAE Grade 2: Persistent or recurrent that does not resolve with maximal supportive measures to baseline or Grade 1 within 7 days	Suspend dose until toxicity resolves to baseline or Grade ≤1	Resume at reduced dose
CTCAE Grade 3 or 4	Suspend dose until toxicity resolves to baseline or Grade ≤1	Resume at reduced dose

*Excluding diarrhea, hematologic toxicity, hepatotoxicity, ILD/pneumonitis, and VTEs

Hepatic Impairment[1]	
Child-Pugh A or B	No dosage adjustments are necessary
Child-Pugh Class C	Reduce dose to once a day

Renal Impairment[1]	
CLcr ≥30-89 mL/min	No dosage adjustments are necessary
CLcr <30 mL/min, end stage renal disease, or in patients on dialysis	Pharmacokinetics of Verzenio are unknown

Concomitant use with CYP3A inhibitors and inducers in patients with starting doses of 200 mg or 150 mg[1]	
Strong CYP3A inhibitor ketoconazole	Avoid
Other strong CYP3A inhibitors If strong CYP3A inhibitor are discontinued, increase the Verzenio dose (after 3-5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor	Reduce dose to 100 mg twice daily[§]
Moderate CYP3A inhibitors	Monitor for adverse reactions and consider 50 mg per dose reduction at a time
Strong and moderate CYP3A inducers	Avoid and consider alternative agents

[§]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[1]

VTEs=venous thromboembollic events; CLcr=creatinine clearance; CYP3A=Cytochrome P450, family 3, subfamily A

Lab abnormalities (all grades; Grade 3 or 4) for **monarchE in ≥10% for Verzenio plus tamoxifen or an aromatase inhibitor with a difference between arms of ≥2%** were increased serum creatinine (99% vs 91%; .5% vs <.1%), decreased white blood cells (89% vs 28%; 19.1% vs 1.1%), decreased neutrophil count (84% vs 23%; 18.7% vs 1.9%), anemia (68% vs 17%; 1% vs .1%), decreased lymphocyte count (59% vs 24%; 13.2 % vs 2.5%), decreased platelet count (37% vs 10%; .9% vs .2%), increased ALT (37% vs 24%; 2.6% vs 1.2%), increased AST (31% vs 18%; 1.6% vs .9%), and hypokalemia (11% vs 3.8%; 1.3% vs 0.2%).

The **most common adverse reactions (all grades, ≥10%)** observed in **MONARCH 3 for Verzenio plus anastrozole or letrozole vs anastrozole or letrozole, with a difference between arms of ≥2%,** were diarrhea (81% vs 30%), fatigue (40% vs 32%), neutropenia (41% vs 2%), infections (39% vs 29%), nausea (39% vs 20%), abdominal pain (29% vs 12%), vomiting (28% vs 12%), anemia (28% vs 5%), alopecia (27% vs 11%), decreased appetite (24% vs 9%), leukopenia (21% vs 2%), creatinine increased (19% vs 4%), constipation (16% vs 12%), ALT increased (16% vs 7%), AST increased (15% vs 7%), rash (14% vs 5%), pruritus (13% vs 9%), cough (13% vs 9%), dyspnea (12% vs 6%), dizziness (11% vs 9%), weight decreased (10% vs 3.1%), influenza-like illness (10% vs 8%), and thrombocytopenia (10% vs 2%).

The **most frequently reported ≥5% Grade 3 or 4 adverse reactions** that occurred in the Verzenio arm vs the placebo arm of **MONARCH 3** were neutropenia (22% vs 1%), diarrhea (9% vs 1.2%), leukopenia (7% vs <1%)), increased ALT (6% vs 2%), and anemia (6% vs 1%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 3 in ≥10% for Verzenio plus anastrozole or letrozole with a difference between arms of ≥2%** were increased serum creatinine (98% vs 84%; 2.2% vs 0%), decreased white blood cells (82% vs 27%; 13% vs 0.6%), anemia (82% vs 28%; 1.6% vs 0%), decreased neutrophil count (80% vs 21%; 21.9% vs 2.6%), decreased lymphocyte count (53% vs 26%; 7.6% vs 1.9%), decreased platelet count (36% vs 12%; 1.9% vs 0.6%), increased ALT (48% vs 25%; 6.6% vs 1.9%), and increased AST (37% vs 23%; 3.8% vs 0.6%).

The most common adverse reactions (all grades, ≥10%) observed in **MONARCH 2 for Verzenio plus fulvestrant vs fulvestrant, with a difference between arms of ≥2%,** were diarrhea (86% vs 25%), neutropenia (46% vs 4%), fatigue (46% vs 32%), nausea (45% vs 23%), infections (43% vs 25%), abdominal pain (35% vs 16%), anemia (29% vs 4%), leukopenia (28% vs 2%), decreased appetite (27% vs 12%), vomiting (26% vs 10%), headache (20% vs 15%), dysgeusia (18% vs 2.7%), thrombocytopenia (16% vs 3%), alopecia (16% vs 1.8%), stomatitis (15% vs 10%), ALT increased (13% vs 5%), pruritus (13% vs 6%), cough (13% vs 11%), dizziness (12% vs 6%), AST increased (12% vs 7%), peripheral edema (12% vs 7%), creatinine increased (12% vs <1%), rash (11% vs 4.5%), pyrexia (11% vs 6%), and weight decreased (10% vs 2.2%).

The **most frequently reported ≥5% Grade 3 or 4 adverse reactions** that occurred in the Verzenio arm vs the placebo arm of **MONARCH 2** were neutropenia (25% vs 1%), diarrhea (13% vs 0.4%), leukopenia (9% vs 0%), anemia (7% vs 1%), and infections (5.7% vs 3.5%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 2 in ≥10% for Verzenio plus fulvestrant with a difference between arms of ≥2%** were increased serum creatinine (98% vs 74%; 1.2% vs 0%), decreased white blood cells (90% vs 33%; 23.7% vs .9%), decreased neutrophil count (87% vs 30%; 32.5% vs 4.2%), anemia (84% vs 34%; 2.6% vs .5%), decreased lymphocyte count (63% vs 32%; 12.2% vs 1.8%), decreased platelet count (53% vs 15%; 2.1% vs 0%), increased ALT (41% vs 32%; 4.6% vs 1.4%), and increased AST (37% vs 25%; 3.9% vs 4.2%).

The **most common adverse reactions (all grades, ≥10%)** observed in **MONARCH 1** with Verzenio were diarrhea (90%), fatigue (65%), nausea (64%), decreased appetite (45%), abdominal pain (39%), neutropenia (37%), vomiting (35%), infections (31%), anemia (25%), thrombocytopenia (20%), headache (20%), cough (19%), constipation (17%), leukopenia (17%), arthralgia (15%), dry mouth (14%), weight decreased (14%), stomatitis (14%), creatinine increased (13%), alopecia (12%), dysgeusia (12%), pyrexia (11%), dizziness (11%), and dehydration (10%).

The **most frequently reported ≥5% Grade 3 or 4 adverse reactions** from **MONARCH 1** with Verzenio were diarrhea (20%), neutropenia (24%), fatigue (13%), and leukopenia (5%).

Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 1 with Verzenio were increased serum creatinine (99%; .8%), decreased white blood cells (91%; 28%), decreased neutrophil count (88%; 26.6%), anemia (69%; 0%), decreased lymphocyte count (42%; 13.8%), decreased platelet count (41%; 2.3%), increased ALT (31%; 3.1%), and increased AST (30%; 3.8%).

Strong and moderate CYP3A inhibitors increased the exposure of abemaciclib plus its active metabolites to a clinically meaningful extent and may lead to increased toxicity. Avoid concomitant use of ketoconazole. Ketoconazole is predicted to increase the AUC of abemaciclib by up to 16-fold. 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 with concomitant use of strong CYP3A inhibitors other than ketoconazole. 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 with concomitant use of strong CYP3A inhibitors. If a patient taking Verzenio discontinues a strong CYP3A inhibitor, increase the Verzenio dose (after 3 to 5 half-lives of the inhibitor) to the dose that was used before starting the inhibitor. With concomitant use of moderate CYP3A inhibitors, monitor for adverse reactions and consider reducing the Verzenio dose in 50 mg decrements. Patients should avoid grapefruit products.

Avoid concomitant use of strong or moderate CYP3A inducers and consider alternative agents. Coadministration of strong or moderate CYP3A inducers decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity.

With severe hepatic impairment (Child-Pugh C), reduce the Verzenio dosing frequency to once daily. The pharmacokinetics of Verzenio in patients with **severe renal impairment** (CLcr <30 mL/min), end stage renal disease, or in patients on dialysis is unknown. No dosage adjustments are necessary in patients with mild or moderate hepatic (Child-Pugh A or B) and/or renal impairment (CLcr ≥30-89 mL/min).

Please see full Prescribing Information for Verzenio.

AL HCP ISI 12OCT2021

References:

1. Verzenio (abemaciclib). Prescribing information. Lilly USA, LLC.
2. Hamilton EP, Kim JH, Eigeliene N, et al. Efficacy and safety results by age in monarchE: Adjuvant abemaciclib combined with endocrine therapy (ET) in patients with HR+, HER2-, node-positive, high-risk early breast cancer (EBC). Presented at American Society of Clinical Oncology (ASCO) 59th Annual Meeting; Chicago, IL; June 26, 2023.
3. National Cancer Institute. Common Terminology Criteria for Adverse Events (CTCAE). Version 5.0; 2017.