Beizray™
(docetaxel) injection,
for intravenous use

Beizray Dosing Guide

INDICATIONS

Beizray is a microtubule inhibitor indicated for:

- **Breast Cancer (BC):** single agent for locally advanced or metastatic BC after chemotherapy failure; and with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive BC
- **Non-small Cell Lung Cancer (NSCLC):** single agent for locally advanced or metastatic NSCLC after platinum therapy failure; and with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC
- **Castration-Resistant Prostate Cancer (CRPC):** with prednisone in metastatic castration-resistant prostate cancer
- **Gastric Adenocarcinoma (GC):** with cisplatin and fluorouracil for untreated, advanced GC, including the gastroesophageal junction
- **Squamous Cell Carcinoma of the Head and Neck (SCCHN):** with cisplatin and fluorouracil for induction treatment of locally advanced SCCHN

IMPORTANT SAFETY INFORMATION

WARNING: TOXIC DEATHS, HEPATOTOXICITY, NEUTROPENIA, HYPERSENSITIVITY REACTIONS, and FLUID RETENTION

- **Treatment-related mortality associated with BEIZRAY is increased in patients with abnormal liver function, in patients receiving higher doses, and in patients with non-small cell lung carcinoma and a history of prior treatment with platinum-based chemotherapy who receive BEIZRAY as a single agent at a dose of 100 mg/m^2.**
- **Avoid the use of BEIZRAY in patients with bilirubin > upper limit of normal (ULN), or to patients with AST and/or ALT >1.5 x ULN concomitant with alkaline phosphatase >2.5 x ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of severe neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death. Patients with isolated elevations of transaminase >1.5 x ULN also had a higher rate of febrile neutropenia. Measure bilirubin, AST or ALT, and alkaline phosphatase prior to each cycle of BEIZRAY.**
- **Do not administer BEIZRAY to patients with neutrophil counts of <1500 cells/mm^3. Monitor blood counts frequently as neutropenia may be severe and result in infection.**
- **Do not administer BEIZRAY to patients who have a history of severe hypersensitivity reactions to docetaxel. Severe hypersensitivity reactions have been reported in patients despite dexamethasone premedication. Hypersensitivity reactions require immediate discontinuation of the BEIZRAY infusion and administration of appropriate therapy.**
- **Severe fluid retention occurred in 6.5% (6/92) of patients despite use of dexamethasone premedication. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites).**

Please see Important Safety Information continued throughout and accompanying full Prescribing Information, including Boxed WARNING. Also available at the QR code.

Dosage Forms and Strengths[1]

BEIZRAY™ (docetaxel) injection is a clear, colorless liquid supplied as follows:

NDC 70710-2093-4
BEIZRAY 160 mg kit

Consisting of the following:

- Two single-dose vials of BEIZRAY: 80 mg/4 mL each
- One single-dose vial of IV Solution Stabilizer: 50 mL of 25% Albumin Human USP solution for infusion; a clear and slightly viscous solution

NDC 70710-2091-3
BEIZRAY 80 mg kit

consisting of the following:

- One single-dose vial of BEIZRAY: 80 mg/4 mL
- One single-dose vial of IV Solution Stabilizer: 50 mL of 25% Albumin Human USP solution for infusion; a clear and slightly viscous solution

NDC 70710-2092-8
BEIZRAY carton

Containing one **single-dose vial***:

- 20 mg/mL

*Beizray is also supplied in an 80mg\4mL single-dose vial (not available in U.S.)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

Welcome

This dosing guide provides step-by-step instructions for the preparation, dosing, and administration of Beizray™ (docetaxel) injection, for intravenous use in accordance with the Prescribing Information.

Important Dosage and Administration[1] Instructions

- Do **not** substitute BEIZRAY for or with other docetaxel products because BEIZRAY has different administration instructions from other docetaxel products.
- For all indications, toxicities may warrant dosage adjustments.
- Administer in a facility equipped to manage possible complications (e.g., anaphylaxis).
- See additional premedication recommendations for the indicated populations.

J9174

All Beizray NDCs (National Drug Code) crosswalk to J9174

IMPORTANT SAFETY INFORMATION (Continued)

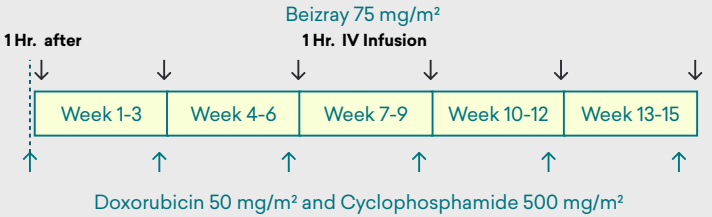
CONTRAINDICATIONS
BEIZRAY is contraindicated in patients with:
• neutrophil counts of <1500 cells/mm^3
• a history of severe hypersensitivity reactions to docetaxel. Severe reactions, including anaphylaxis, have occurred.

Recommended Dosage for Breast Cancer[1]

For the adjuvant treatment of operable node-positive breast cancer

Recommended Dosage

- The recommended BEIZRAY dosage is 75 mg/m² administered 1 hour after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every 3 weeks for 6 courses.
- Prophylactic G-CSF may be used to mitigate the risk of hematological toxicities.



Dosage Adjustments during Treatment

BEIZRAY in combination with doxorubicin and cyclophosphamide should be administered when the neutrophil count is ≥1,500 cells/mm³.

Adverse reaction	Dosage modification
Febrile neutropenia	G-CSF in all subsequent cycles. Patients who continue to experience this reaction should remain on G-CSF and have their Beizray dose reduced to 60 mg/m².
Grade 3 or 4 stomatitis	Decrease Beizray dose to 60 mg/m².
Severe or cumulative cutaneous reactions or moderate neurosensory signs and/or symptoms	Reduce 75 mg/m² to 60 mg/m². If the patient continues to experience these reactions at 60 mg/m², treatment should be discontinued.

IMPORTANT SAFETY INFORMATION (Continued)

WARNINGS AND PRECAUTIONS
Toxic Deaths, Hepatotoxicity, Neutropenia, Hypersensitivity Reactions, and Fluid Retention (See Boxed WARNING)

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

Recommended Dosage for Breast Cancer[1]

For locally advanced or metastatic breast cancer after failure of prior chemotherapy

Recommended Dosage

- The recommended dosage of BEIZRAY is 60 mg/m² to 100 mg/m² administered intravenously over 1 hour every 3 weeks.

Dosage Adjustments during Treatment

Adverse reaction	Dosage modification
Patients who are dosed initially at 100 mg/m² and who experience either: • Febrile neutropenia, neutrophils <500 cells/mm³ for more than 1 week • Severe or cumulative cutaneous reactions.	Reduce from 100 mg/m² to 75 mg/m². If the patient continues to experience these reactions, the dosage should either be decreased from 75 mg/m² to 55 mg/m² or the treatment should be discontinued.

- Conversely, patients who are dosed initially at 60 mg/m² and who do not experience febrile neutropenia, neutrophils <500 cells/mm³ for more than 1 week, severe or cumulative cutaneous reactions, or severe peripheral neuropathy during BEIZRAY therapy may tolerate higher doses.
- Patients who develop ≥ grade 3 peripheral neuropathy should have BEIZRAY treatment discontinued entirely.

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

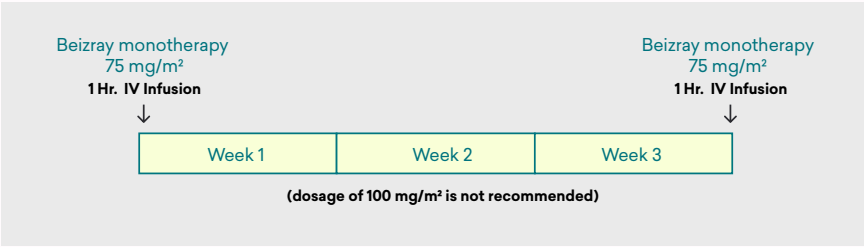
Second primary malignancies: In patients treated with BEIZRAY-containing regimens, monitor for delayed AML, MDS, NHL, and renal cancer.

Recommended Dosage for Non-small Cell Lung Cancer[1]

For treatment after failure of prior platinum-based chemotherapy

Recommended Dosage

- The recommended dosage of BEIZRAY monotherapy is 75 mg/m² administered intravenously over 1 hour every 3 weeks.



In patients previously treated with chemotherapy, a dosage of 100 mg/m² is not recommended because this dosage was associated with increased hematologic toxicity, infection, and treatment-related mortality in randomized controlled trials.

Dosage Adjustments during Treatment

Adverse reaction	Dosage modification
Patients who are dosed initially at 75 mg/m² and who experience either: • Febrile neutropenia, neutrophils <500 cells/mm³ for more than one week. • Severe or cumulative cutaneous reactions. • Other grade 3/4 non-hematological toxicities.	Withhold treatment until resolution of the toxicity and then resume at 55 mg/m².
≥Grade 3 peripheral neuropathy.	Discontinue BEIZRAY treatment entirely.

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

Cutaneous reactions: Reactions including erythema of the extremities with edema followed by desquamation may occur. Severe cutaneous adverse reactions have been reported. Severe skin toxicity may require dose adjustment or permanent treatment discontinuation.

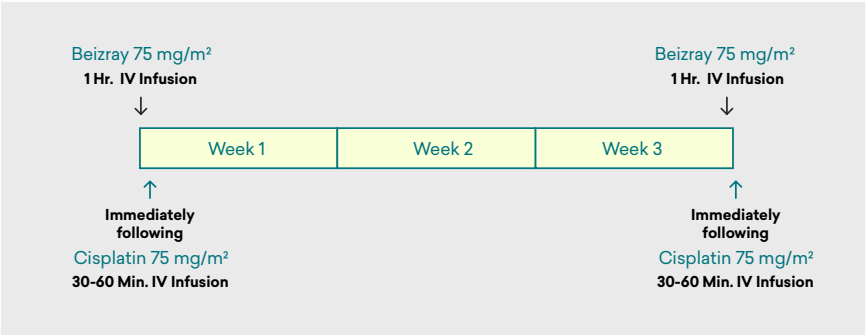
Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

Recommended Dosage for Non-small Cell Lung Cancer[1]

For chemotherapy-naive patients with cisplatin for unresectable, locally advanced or metastatic untreated NSCLC

Recommended Dosage

- For chemotherapy-naive patients, the recommended dosage of BEIZRAY is 75 mg/m² administered intravenously over 1 hour immediately followed by cisplatin 75 mg/m² over 30–60 minutes every 3 weeks.



Dosage Adjustments during Treatment

Adverse reaction	Dosage modification
Patients who are dosed initially at BEIZRAY 75 mg/m² in combination with cisplatin, whose nadir of platelet count during the previous course of therapy is <25,000 cells/mm³, in patients who experience febrile neutropenia, and in patients with serious non-hematologic toxicities.	Dosage in subsequent cycles should be reduced to 65 mg/m². In patients who require a further dose reduction, a dose of 50 mg/m² is recommended. For cisplatin dosage adjustments, see manufacturers' prescribing information.

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

Neurologic reactions: Reactions including paresthesia, dysesthesia, and pain may occur. Severe neurosensory symptoms require dose adjustment or discontinuation if persistent.

Recommended Dosage for Prostate Cancer[1]

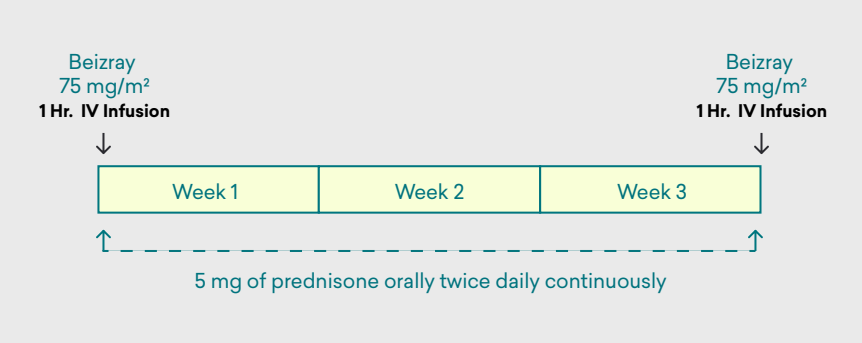
For metastatic castration-resistant prostate cancer

Premedication

- Given the concurrent use of prednisone, the recommended premedication regimen is oral dexamethasone 8 mg at 12 hours, 3 hours, and 1 hour before the BEIZRAY infusion

Recommended Dosage

- The recommended dosage of BEIZRAY is 75 mg/m² every 3 weeks as a 1-hour intravenous infusion.
- Recommend concomitant use of 5 mg of prednisone orally twice daily continuously.



Dosage Adjustments during Treatment

BEIZRAY should be administered when the neutrophil count is ≥1,500 cells/mm³.

Adverse reaction	Dosage modification
Patients who experience either: • Febrile neutropenia, neutrophils <500 cells/mm³ for more than one week. • Severe or cumulative cutaneous reactions. • Moderate neurosensory signs and/or symptoms.	Reduce dosage from 75 mg/m² to 60 mg/m². If the patient continues to experience these reactions at 60 mg/m², the treatment should be discontinued.

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

Eye disorders: Cystoid macular edema (CME) has been reported and requires treatment discontinuation.

Asthenia: Severe asthenia may occur and may require treatment discontinuation.

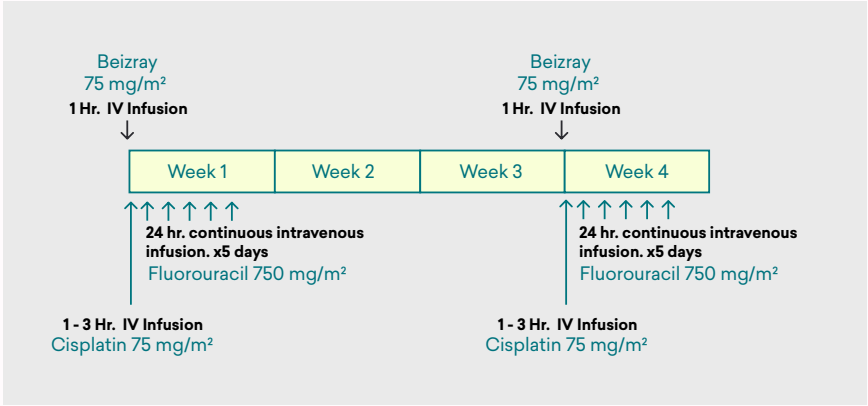
Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

Recommended Dosage for Gastric Adenocarcinoma[1]

For advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, in patients who have not received prior chemotherapy for advanced disease

Recommended Dosage

- The recommended dosage of BEIZRAY is 75 mg/m² as a 1-hour intravenous infusion
- Followed by cisplatin 75 mg/m², as a 1 to 3 hour intravenous infusion (both on day 1 only)
- Followed by fluorouracil 750 mg/m² per day given as a 24-hour continuous intravenous infusion for 5 days, starting at the end of the cisplatin infusion.
- Repeat treatment every 3 weeks.
- Must receive premedication with antiemetics and appropriate hydration for cisplatin administration.



Dosage Adjustments during Treatment

See Page 12 for dose modifications for Gastric or Head and Neck Cancer

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

Embryo-fetal toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception.

Alcohol content: The alcohol content in a dose of BEIZRAY Injection may affect the central nervous system. This may include impairment of a patient's ability to drive or use machines immediately after infusion.

Recommended Dosage for Squamous Cell Carcinoma of the Head and Neck[1]

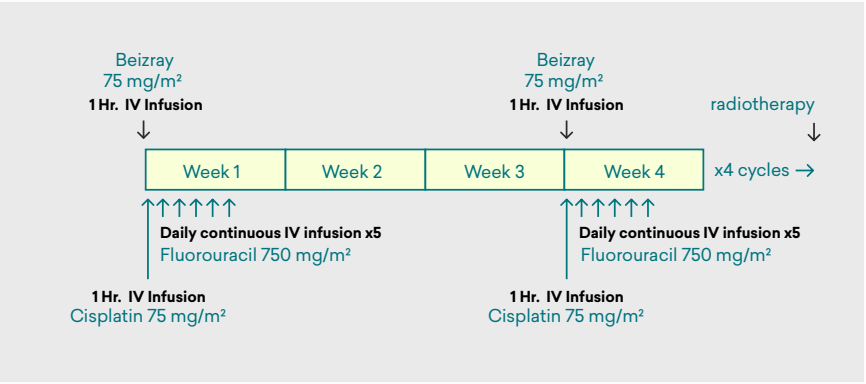
With cisplatin and fluorouracil for induction treatment of locally advanced SCCHN followed by radiotherapy (TAX323)

Premedication

- Must receive premedication with antiemetics, and appropriate hydration (prior to and after cisplatin administration).
- Prophylaxis for neutropenic infections should be administered.
- All patients treated on the BEIZRAY containing arms of the TAX323 and TAX324 studies received prophylactic antibiotics.

Recommended Dosage

- For the induction treatment of locally advanced inoperable SCCHN, the recommended dose of BEIZRAY is 75 mg/m^2 as a 1-hour intravenous infusion
- Followed by cisplatin 75 mg/m^2 intravenously over 1 hour, on day 1,
- Followed by fluorouracil as a continuous intravenous infusion at 750 mg/m^2 per day for 5 days.
- This regimen is administered every 3 weeks for 4 cycles.
- Following chemotherapy, patients should receive radiotherapy.



Dosage Adjustments during Treatment

See Page 12 for dose modifications for Gastric or Head and Neck Cancer

IMPORTANT SAFETY INFORMATION (Continued)
WARNINGS AND PRECAUTIONS (Continued)

Tumor lysis syndrome: Tumor lysis syndrome has been reported. Patients at risk should be well hydrated and closely monitored during treatment.

Transmissible Infectious Agents: BEIZRAY final infusion solution contains albumin derived from human blood, which has a theoretical risk of viral transmission.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

Recommended Dosage for Squamous Cell Carcinoma of the Head and Neck[1]

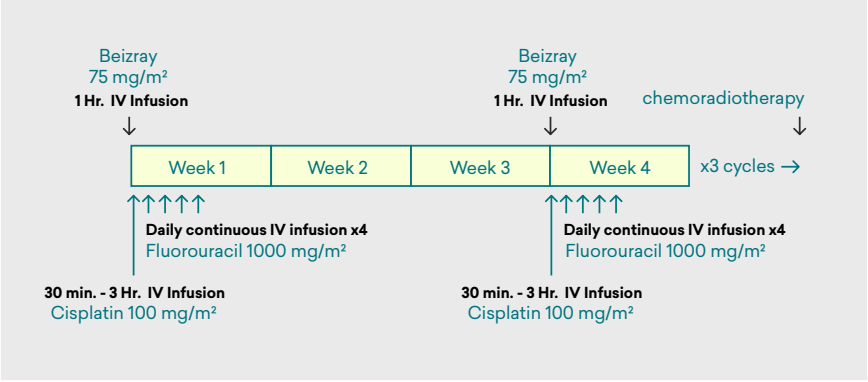
For induction treatment of locally advanced SCCHN followed by Chemoradiotherapy (TAX324)

Premedication

- Must receive premedication with antiemetics, and appropriate hydration (prior to and after cisplatin administration).
- Prophylaxis for neutropenic infections should be administered.
- All patients treated on the BEIZRAY containing arms of the TAX323 and TAX324 studies received prophylactic antibiotics.

Recommended Dosage

- For the induction treatment of patients with locally advanced (unresectable, low surgical cure, or organ preservation) SCCHN, the recommended dose of BEIZRAY is 75 mg/m^2 as a 1-hour intravenous infusion on day 1,
- Followed by cisplatin 100 mg/m^2 administered as a 30-minute to 3-hour infusion,
- Followed by fluorouracil 1000 mg/m^2/day as a continuous infusion from day 1 to day 4.
- This regimen is administered every 3 weeks for 3 cycles.
- Following chemotherapy, patients should receive chemoradiotherapy.



Dosage Adjustments during Treatment

See Page 12 for dose modifications for Gastric or Head and Neck Cancer

IMPORTANT SAFETY INFORMATION (Continued)

ADVERSE REACTIONS

The most serious adverse reactions from BEIZRAY are Toxic Deaths, Hepatic Impairment, Hematologic Effects, Enterocolitis and Neutropenic Colitis, Hypersensitivity Reactions, Fluid Retention, Second Primary Malignancies, Cutaneous Reactions, Neurologic Reactions, Eye Disorders, Asthenia, Alcohol Content, Tumor Lysis Syndrome.

Dose modifications for Gastric or Head and Neck Cancer[1]

BEIZRAY in combination with cisplatin and fluorouracil in gastric cancer or head and neck cancer

Patients treated with BEIZRAY in combination with cisplatin and fluorouracil must receive antiemetics and appropriate hydration according to current institutional guidelines. In both studies, G-CSF was recommended during the second and/or subsequent cycles in case of febrile neutropenia, or documented infection with neutropenia, or neutropenia lasting more than 7 days.

Adverse reaction	Dosage modification
An episode of febrile neutropenia, prolonged neutropenia or neutropenic infection despite G-CSF use.	BEIZRAY dose should be reduced from 75 mg/m² to 60 mg/m². If subsequent episodes of complicated neutropenia occur the BEIZRAY dose should be reduced from 60 mg/m² to 45 mg/m².
Grade 4 thrombocytopenia.	BEIZRAY dose should be reduced from 75 mg/m² to 60 mg/m².

Do not retreat patients with subsequent cycles of BEIZRAY until neutrophils recover to a level >1,500 cells/mm³. Avoid retreating patients until platelets recover to a level >100,000 cells/mm³. Discontinue treatment if these toxicities persist.

Recommended dose modifications for toxicities in patients treated with BEIZRAY in combination with cisplatin and fluorouracil are shown in Table 1.

Table 1: Recommended Dose Modifications for Toxicities in Patients Treated with BEIZRAY in Combination with Cisplatin and Fluorouracil

Toxicity	Dosage adjustment
Diarrhea grade 3	First episode: reduce fluorouracil dose by 20%. Second episode: then reduce BEIZRAY dose by 20%.
Diarrhea grade 4	First episode: reduce BEIZRAY and fluorouracil doses by 20%. Second episode: discontinue treatment.
Stomatitis/ mucositis grade 3	First episode: reduce fluorouracil dose by 20%. Second episode: stop fluorouracil only, at all subsequent cycles. Third episode: reduce BEIZRAY dose by 20%.
Stomatitis/ mucositis grade 4	First episode: stop fluorouracil only, at all subsequent cycles. Second episode: reduce BEIZRAY dose by 20%.

Liver dysfunction: In case of AST/ALT >2.5 to ≤5 × ULN and AP ≤2.5 × ULN, or AST/ALT >1.5 to ≤5 × ULN and AP >2.5 to ≤5 × ULN, BEIZRAY should be reduced by 20%.

In case of AST/ALT >5 × ULN and/or AP >5 × ULN BEIZRAY should be stopped.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed WARNING

The dose modifications for cisplatin and fluorouracil in the gastric cancer study are provided below.

Cisplatin dose modifications and delays

Peripheral neuropathy: A neurological examination should be performed before entry into the study, and then at least every 2 cycles and at the end of treatment. In the case of neurological signs or symptoms, more frequent examinations should be performed and the following dose modifications can be made according to NCI-CTCAE grade:

- Grade 2: Reduce cisplatin dose by 20%.
- Grade 3: Discontinue treatment.

Ototoxicity: In the case of grade 3 toxicity, discontinue treatment.

Nephrotoxicity: In the event of a rise in serum creatinine ≥ grade 2 (>1.5 × normal value) despite adequate rehydration, CrCl should be determined before each subsequent cycle and the following dose reductions should be considered (see Table 2).

For other cisplatin dosage adjustments, also refer to the manufacturers' prescribing information.

Table 2: Dose Reductions for Evaluation of Creatinine Clearance

Creatinine clearance result before next cycle	Cisplatin dose next cycle
CrCl ≥60 mL/min	Full dose of cisplatin was given. CrCl was to be repeated before each treatment cycle.
CrCl between 40 and 59 mL/min	Dose of cisplatin was reduced by 50% at subsequent cycle. If CrCl was >60 mL/min at end of cycle, full cisplatin dose was reinstituted at the next cycle. If no recovery was observed, then cisplatin was omitted from the next treatment cycle.
CrCl <40 mL/min	Dose of cisplatin was omitted in that treatment cycle only. If CrCl was still <40 mL/min at the end of cycle, cisplatin was discontinued. If CrCl was >40 and <60 mL/min at end of cycle, a 50% cisplatin dose was given at the next cycle. If CrCl was >60 mL/min at end of cycle, full cisplatin dose was given at next cycle.

CrCl = Creatinine clearance

IMPORTANT SAFETY INFORMATION (Continued)

ADVERSE REACTIONS (Continued)

The most common adverse reactions across all docetaxel indications are infections, neutropenia, anemia, febrile neutropenia, hypersensitivity, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, nausea, diarrhea, vomiting, mucositis, alopecia, skin reactions, and myalgia. Incidence varies depending on the indication.

Dose modifications for Gastric or Head and Neck Cancer (Continued)

Fluorouracil dose modifications and treatment delays

For diarrhea and stomatitis, see Table 1.

In the event of grade 2 or greater plantar-palmar toxicity, fluorouracil should be stopped until recovery. The fluorouracil dosage should be reduced by 20%.

For other greater than grade 3 toxicities, except alopecia and anemia, chemotherapy should be delayed (for a maximum of 2 weeks from the planned date of infusion) until resolution to grade ≤1 and then recommenced, if medically appropriate.

For other fluorouracil dosage adjustments, also refer to the manufacturers' prescribing information.

Combination Therapy with Strong CYP3A4 Inhibitors

Avoid using concomitant strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin and voriconazole). There are no clinical data with a dose adjustment in patients receiving strong CYP3A4 inhibitors. Based on extrapolation from a pharmacokinetic study with ketoconazole in 7 patients, consider a 50% docetaxel dose reduction if patients require coadministration of a strong CYP3A4 inhibitor.

Corticosteroid Premedication Regimen[1]

All patients should be premedicated with oral corticosteroids (see below for prostrate cancer) such as dexamethasone 16 mg per day (e.g., 8 mg twice daily) for 3 days starting 1 day prior to BEIZRAY administration in order to reduce the incidence and severity of fluid retention as well as the severity of hypersensitivity reactions.

For metastatic castration-resistant prostate cancer, given the concurrent use of prednisone, the recommended premedication regimen is oral dexamethasone 8 mg at 12 hours, 3 hours, and 1 hour before the BEIZRAY infusion.

To report SUSPECTED ADVERSE REACTIONS, contact Zydus Pharmaceuticals (USA) Inc. at 1-877-993-8779 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information, including Boxed WARNING.

REFERENCE:

1. Beizray™ (docetaxel) Prescribing Information. Zydus Pharmaceuticals (USA) Inc.

Please find printed full Prescribing Information in this pocket

Preparing Beizray

Calculate: *Beizray:* **Beizray (docetaxel) dose (mg/m²) x Body Surface Area (m²) ÷ 20 mg/mL = Beizray (docetaxel) dose (mL)**

Select IV bag: **Beizray ≤ 8.8 mL = 500 mL**
Beizray > 8.8 mL = 1,000 mL

Albumin: **Beizray (docetaxel) dose (mL) x 6 = Albumin dose (mL)**

Albumin: Add to IV bag, mix by gently inverting bag at least 5 times. Do not shake.

Beizray: Add to IV bag, mix by gently inverting bag at least 10 times. Do not shake.

Refer to the Prescribing Information for complete preparation and administration instructions.

Scan QR code to see further information on Beizray on our website

Beizray Calculation Examples

Beizray™ (docetaxel) injection, for intravenous use

The following chart is for informational purposes only and is an example intended to guide preparation once a calculated dose has been obtained.

Calculated dose should be based on the recommended dose by indication and body surface area of your patient per the Prescribing Information.*

Calculated Beizray Dose (mg)	25% Albumin (mL)	Calculated Beizray Volume (mL)	160 mg (8 mL) Kit	80mg (4 mL) Kit	20mg (1 mL) Vial	Bag Size (mL)	Total Volume (mL)
100	30	5		1	1	500	535
105	31.5	5.25		1	2	500	536.75
110	33	5.5		1	2	500	538.5
115	34.5	5.75		1	2	500	540.25
120	36	6		1	2	500	542
125	37.5	6.25		1	2	500	543.75
130	39	6.5		1	3	500	545.5
135	40.5	6.75		1	3	500	547.25
140	42	7		1	3	500	549
145	43.5	7.25	1			500	550.75
150	45	7.5	1			500	552.5
155	46.5	7.75	1			500	554.25
160	48	8	1			500	556
165	49.5	8.25	1		1	500	557.75
170	51	8.5		2	1	500	559.5
175	52.5	8.75		2	1	500	561.25
180	54	9		2	1	1000	1063
185	55.5	9.25		2	2	1000	1064.75
190	57	9.5		2	2	1000	1066.5

* Data on file

Please see accompanying full Prescribing Information, including Boxed WARNING.