

BeizrayTM is the first and only FDA approved docetaxel injection to be mixed with albumin before administration.

Drug Information Sheet for HCPs

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



Please see accompanying full [Prescribing Information](#), including [Boxed Warning](#), also available at the QR code.

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/m².**
- **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/mm³. 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).**

Beizray™ (docetaxel) Injection Drug Information Sheet

Highlights of Prescribing Information:

These highlights do not include all the information needed to use Beizray safely and effectively. See full prescribing information for Beizray.

Product Identification

Brand Name	Beizray™ (docetaxel) Injection, for intravenous use
Generic Name	Docetaxel
Dosage Form	Injection, solution for intravenous (IV) use
Initial U.S. Approval	1996

Contraindications

- Hypersensitivity to docetaxel
- Neutrophil counts of <1500 cells/mm³

Dosage and Administration

- **Do not substitute Beizray for or with other docetaxel products.**
Administer in a facility equipped to manage possible complications (e.g., anaphylaxis). Administer intravenously (IV) over 1 hour every 3 weeks.
- **BC (locally advanced or metastatic):** 60 mg/m² to 100 mg/m² (single agent)
- **BC (adjuvant):** 75 mg/m² administered 1 hour after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every 3 weeks for 6 cycles
- **NSCLC (after platinum therapy failure):** 75 mg/m² (single agent)
- **NSCLC (chemotherapy naïve):** 75 mg/m² followed by cisplatin 75 mg/m²
- **CRPC:** 75 mg/m² with prednisone 5 mg twice daily continuously
- **GC:** 75 mg/m² followed by cisplatin 75 mg/m² (both on day 1 only) followed by fluorouracil 750 mg/m² per day as a 24-hour IV (days 1-5), starting at the end of cisplatin infusion
- **SCCHN:** 75 mg/m² followed by cisplatin 75 mg/m² IV (day 1), followed by fluorouracil 750 mg/m² per day as a 24-hour IV (days 1-5), starting at the end of cisplatin infusion; for 4 cycles
- **SCCHN (alternate):** 75 mg/m² followed by cisplatin 100 mg/m² IV (day 1), followed by fluorouracil 1000 mg/m² per day as a 24-hour IV (days 1-4); for 3 cycles

For all patients:

- Premedicate with oral corticosteroids
- Adjust dose as needed

Dosage Forms and Strengths

Beizray (docetaxel) injection is supplied as follows:

Beizray 80 mg kit contains:

- One single-dose vial of Beizray: 80 mg/4 mL
- One single-dose vial of IV Solution Stabilizer (50 mL, 25% Albumin Human USP solution)

Beizray 160 mg kit contains:

- Two single-dose vials of Beizray: 80 mg/4 mL each
- One single-dose vial of IV Solution Stabilizer (50 mL, 25% Albumin Human USP solution)

Beizray carton containing one 20mg/mL single-dose vial:

- 20 mg/mL

Beizray carton containing one 80mg/mL single-dose vial: (not available in the US)

- 80 mg/4mL

Store at 20–25 °C (68–77 °F); excursions permitted from 15–30 °C (59–86 °F). Protect from light. Do not freeze.

Patient Counseling Information

- **Bone Marrow Suppression:** Advise patients about routine blood tests to monitor neutropenia, thrombocytopenia, and anemia. Report fever immediately.
- **Enterocolitis and Neutropenic Colitis:** Inform patients to report symptoms like abdominal pain, tenderness, or diarrhea, with or without fever.
- **Hypersensitivity Reactions:** Ask about prior paclitaxel therapy and instruct patients to report signs of allergic reactions (e.g., trouble breathing, swelling, rash).
- **Fluid Retention:** Advise patients to report signs like swelling, weight gain, or shortness of breath.
- **Second Primary Malignancies:** Inform patients about the risk of developing new cancers during and after treatment.
- **Cutaneous Reactions:** Instruct patients to report severe skin reactions (e.g., redness, peeling, blistering).
- **Neurologic Reactions:** Advise patients to report symptoms like numbness, tingling, or weakness.
- **Eye Disorders:** Inform patients to report vision changes or excessive tearing.
- **Gastrointestinal Reactions:** Explain common side effects like nausea, vomiting, diarrhea, and constipation; report severe events.
- **Cardiac Disorders:** Advise patients to report irregular and/or rapid heartbeat, shortness of breath, dizziness, or fainting.
- **Other Common Side Effects:** Include alopecia, asthenia, anorexia, dysgeusia, mucositis, myalgia, nail disorders, and pain. Report serious events.
- **Corticosteroids:** Stress the importance of compliance with oral corticosteroid regimens.
- **Embryo-Fetal Toxicity:** Warn about fetal harm and advise effective contraception during treatment (females: 2 months; males: 4 months post-treatment).
- **Lactation:** Advise against breastfeeding during treatment and for 1 week after the last dose.
- **Infertility:** Inform males of potential fertility impairment.
- **Alcohol Content:** Explain possible effects on the central nervous system and caution against driving or operating machinery.
- **Tumor Lysis Syndrome:** Advise patients to report symptoms like nausea, confusion, or irregular heartbeat immediately.
- **Driving or Operating Machines:** Warn about potential impairment due to side effects or alcohol content.
- **Drug Interactions:** Stress the importance of providing a complete list of medications to avoid interactions.

Adverse Reactions

The most serious adverse reactions from Beizray are:

- Toxic Deaths [see Boxed Warning, Warnings and Precautions]
- Hepatic Impairment [see Boxed Warning, Warnings and Precautions]
- Hematologic Effects [see Boxed Warning, Warnings and Precautions]
- Enterocolitis and Neutropenic Colitis [see Warnings and Precautions]
- Hypersensitivity Reactions [see Boxed Warning, Warnings and Precautions]
- Fluid Retention [see Boxed Warning, Warnings and Precautions]
- Second Primary Malignancies [see Warnings and Precautions]
- Cutaneous Reactions [see Warnings and Precautions]
- Neurologic Reactions [see Warnings and Precautions]
- Eye Disorders [see Warnings and Precautions]
- Asthenia [see Warnings and Precautions]
- Alcohol Content [see Warnings and Precautions]
- Tumor Lysis Syndrome [see Warnings and Precautions]

Please see additional details on page 5-7 of this document and in the full Prescribing Information.

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.

Adverse reactions are described according to indication. 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.

Responding patients may not experience an improvement in performance status on therapy and may experience worsening. The relationship between changes in performance status, response to therapy, and treatment-related side effects has not been established.

Use in Specific Populations

This summary provides key highlights only. Refer to full prescribing information for complete details.

Pregnancy

Beizray (docetaxel) can cause fetal harm when administered to a pregnant woman, based on animal data and its mechanism of action. In animal studies, embryo-fetal toxicity and intrauterine mortality occurred at doses approximately 0.02 and 0.003 times the daily maximum recommended human dose based on body surface area. Beizray contains alcohol, which has been associated with fetal harm including central nervous system abnormalities, behavioral disorders, and impaired intellectual development. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Baseline risk in clinically recognized U.S. pregnancies: major birth defects 2–4%, miscarriage 15–20%.

Lactation

There is no information regarding the presence of docetaxel in human milk, or on its effects on milk production or the breastfed child. No lactation studies in animals have been conducted. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 week after the last dose.

Females and Males of Reproductive Potential

Based on findings in animals, Beizray can cause fetal harm when administered to a pregnant woman.

Pregnancy testing: Verify pregnancy status in females of reproductive potential prior to initiating Beizray.

Contraception:

Females: Based on genetic toxicity findings, advise females of reproductive potential to use effective contraception during treatment and for 2 months after the last dose.

Males: Based on genetic toxicity findings, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

Infertility: Based on findings in animal studies, Beizray may impair fertility in males of reproductive potential.

Pediatric Use

The alcohol content of Beizray Injection should be taken into account when given to pediatric patients. The efficacy of Beizray in pediatric patients, either as monotherapy or in combination, has not been established. The overall safety profile was generally consistent with that observed in adults.

Monotherapy (n=239): Response rates were low (one complete response, four partial responses).

Combination TCF (n=50, nasopharyngeal carcinoma): One complete response (2%) observed.

Pharmacokinetic parameters (clearance and AUC) were comparable to adults.

Geriatric Use

Dose selection for elderly patients should be cautious, reflecting greater frequency of decreased hepatic, renal, or cardiac function and concomitant disease or other drug therapy.

NSCLC: Patients ≥65 years experienced higher rates of diarrhea, infection, peripheral edema, and stomatitis compared to younger patients.

Prostate cancer: Patients ≥65 years experienced higher rates of anemia, infection, nail changes, anorexia, and weight loss.

Gastric cancer: Elderly patients had a higher incidence of serious adverse reactions (lethargy, stomatitis, diarrhea, dizziness, edema, febrile neutropenia).

Breast and head & neck cancer: Limited numbers of elderly patients; no identified differences in response.

Elderly patients treated with TCF regimens should be closely monitored.

Hepatic Impairment

Avoid Beizray in patients with bilirubin > ULN, or AST and/or ALT >1.5 × ULN concomitant with alkaline phosphatase >2.5 × ULN. The alcohol content of Beizray Injection should be taken into account when given to patients with hepatic impairment.

Overdosage

- **No Known Antidote:** In case of overdose, monitor vital functions closely in a specialized unit.
- **Complications:** Anticipated issues include bone marrow suppression, peripheral neurotoxicity, and mucositis.
- **Treatment:** Administer therapeutic G-CSF as soon as possible and provide symptomatic care as needed.
- **Reported Cases:** Patients receiving 150-200 mg/m² experienced severe neutropenia, mild asthenia, cutaneous reactions, and paresthesia but recovered without incident.

Drug Interactions

Docetaxel is a CYP3A4 substrate. Its metabolism may be affected by concomitant administration of drugs that induce, inhibit, or are metabolized by CYP3A4.

Potent CYP3A4 inhibitors: In vivo, coadministration with ketoconazole increased docetaxel exposure 2.2-fold. Protease inhibitors, particularly ritonavir, may also increase docetaxel exposure.

Clinical management: Concomitant use of Beizray and CYP3A4 inhibitors should be avoided. If coadministration with a potent CYP3A4 inhibitor cannot be avoided, closely monitor for toxicity and consider a Beizray dose reduction [see Dosage and Administration, Clinical Pharmacology].

Warnings and Precautions

Toxic deaths

Breast cancer

Beizray administered at 100 mg/m² was associated with deaths considered possibly or probably related to treatment in 2.0% (19/965) of metastatic breast-cancer patients, both previously treated and untreated, with normal baseline liver function, and in 11.5% (7/61) of patients with various tumor types who had abnormal baseline liver function (AST and/or ALT > 1.5 × ULN together with AP > 2.5 × ULN).

Among patients dosed at 60 mg/m², mortality related to treatment occurred in 0.6% (3/481) of patients with normal liver function and in 3 of 7 patients with abnormal liver function. Approximately half of these deaths occurred during the first cycle. Sepsis accounted for the majority of deaths.

Non-small cell lung cancer

Beizray administered at a dose of 100 mg/m² in patients with locally advanced or metastatic non-small cell lung cancer who had a history of prior platinum-based chemotherapy was associated with increased treatment-related mortality (14% and 5% in two randomized, controlled studies). There were 2.8% treatment-related deaths among the 176 patients treated at the 75 mg/m² dose in the randomized trials. Among patients who experienced treatment-related mortality at the 75 mg/m² dose level, 3 of 5 patients had an ECOG PS of 2 at study entry [see Dosage and Administration, Clinical Studies].

Hepatic impairment: 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.

Avoid Beizray in patients with bilirubin > upper limit of normal (ULN), or in patients with AST and/or ALT > 1.5 × ULN concomitant with alkaline phosphatase > 2.5 × ULN [see Warnings and Precautions].

For patients with isolated elevations of transaminase > 1.5 × ULN, consider Beizray dose modifications [see Dosage and Administration].

Measure bilirubin, AST or ALT, and alkaline phosphatase prior to each cycle of Beizray therapy.

Hematologic effects: Perform frequent peripheral blood-cell counts on all patients receiving Beizray. Do not retreat patients with subsequent cycles of Beizray until neutrophils recover to a level > 1500 cells/mm³ [see Contraindications]. Avoid retreating patients until platelets recover to a level > 100 000 cells/mm³.

A 25% reduction in the dose of Beizray is recommended during subsequent cycles following severe neutropenia (< 500 cells/mm³) lasting 7 days or more, febrile neutropenia, or a grade 4 infection in a Beizray cycle [see Dosage and Administration].

Neutropenia (< 2000 neutrophils/mm³) occurs in virtually all patients given 60 mg/m² to 100 mg/m² of Beizray, and grade 4 neutropenia (< 500 cells/mm³) occurs in 85% of patients given 100 mg/m² and 75% of those given 60 mg/m². Frequent monitoring of blood counts is therefore essential so that dose can be adjusted. Beizray should not be administered to patients with neutrophils < 1500 cells/mm³.

Febrile neutropenia occurred in about 12% of patients given 100 mg/m² but was very uncommon in patients given 60 mg/m². Hematologic responses, febrile reactions and infections, and rates of septic death for different regimens are dose-related [see Adverse Reactions, Clinical Studies].

Three breast-cancer patients with severe liver impairment (bilirubin > 1.7 × ULN) developed fatal gastrointestinal bleeding associated with severe drug-induced thrombocytopenia. In gastric-cancer patients treated with docetaxel in combination with cisplatin and fluorouracil (TCF), febrile neutropenia and/or neutropenic infection occurred in 12% of patients receiving G-CSF compared with 28% who did not. Patients receiving TCF should be closely monitored during the first and subsequent cycles for febrile neutropenia and neutropenic infection [see Dosage and Administration, Adverse Reactions].

Enterocolitis and Neutropenic Colitis: Enterocolitis and neutropenic colitis (typhlitis) have occurred in patients treated with Beizray alone and in combination with other chemotherapeutic agents, despite co-administration of G-CSF. Caution is recommended for patients with neutropenia, particularly those at risk for developing gastrointestinal complications. Enterocolitis and neutropenic enterocolitis may develop at any time and could lead to death as early as the first day of symptom onset. Monitor patients closely from onset of any symptoms of gastrointestinal toxicity. Inform patients to contact their healthcare provider with new or worsening symptoms of gastrointestinal toxicity [see Dosage and Administration, Warnings and Precautions, Adverse Reactions].

Warnings and Precautions (cont.)

Hypersensitivity reactions: Monitor patients closely for hypersensitivity reactions, especially during the first and second infusions. Severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or fatal anaphylaxis have been reported in patients premedicated with 3 days of corticosteroids. Severe hypersensitivity reactions require immediate discontinuation of the Beizray infusion and aggressive therapy. Do not rechallenge patients with a history of severe hypersensitivity reactions with Beizray [see Contraindications].

Patients who have previously experienced a hypersensitivity reaction to paclitaxel may develop a hypersensitivity reaction to docetaxel that may include severe or fatal reactions such as anaphylaxis. Monitor patients with a previous history of hypersensitivity to paclitaxel closely during initiation of Beizray therapy. Hypersensitivity reactions may occur within a few minutes following initiation of a Beizray infusion.

If minor reactions such as flushing or localized skin reactions occur, interruption of therapy is not required. All patients should be premedicated with an oral corticosteroid prior to the initiation of Beizray infusion [see Dosage and Administration].

Fluid retention: Severe fluid retention has been reported following Beizray therapy. Patients should be premedicated with oral corticosteroids prior to each Beizray administration to reduce the incidence and severity of fluid retention [see Dosage and Administration]. Patients with pre-existing effusions should be closely monitored from the first dose for possible exacerbation.

When fluid retention occurs, peripheral edema usually starts in the lower extremities and may become generalized, with a median weight gain of 2 kg.

Among 92 breast-cancer patients premedicated with 3-day corticosteroids, moderate fluid retention occurred in 27.2% and severe fluid retention in 6.5%. The median cumulative dose to onset of moderate or severe fluid retention was 819 mg/m². Nine of 92 patients (9.8%) discontinued treatment due to fluid retention: four with severe and five with mild or moderate retention. The median cumulative dose to discontinuation due to fluid retention was 1021 mg/m².

Fluid retention was completely, but sometimes slowly, reversible with a median of 16 weeks from the last infusion of Beizray to resolution (range 0 to 42+ weeks). Patients developing peripheral edema may be treated with standard measures such as salt restriction and oral diuretics.

Second primary malignancies: Second primary malignancies, notably acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), non-Hodgkin's lymphoma (NHL), and renal cancer, have been reported in patients treated with docetaxel-containing regimens. These adverse reactions may occur several months or years after therapy.

Treatment-related AML or MDS has occurred in patients given anthracyclines and/or cyclophosphamide, including use in adjuvant therapy for breast cancer. In the adjuvant breast-cancer trial (TAX316), AML occurred in 3 of 744 patients who received docetaxel, doxorubicin, and cyclophosphamide (TAC) and in 1 of 736 patients who received fluorouracil, doxorubicin, and cyclophosphamide [see Clinical Studies]. In TAC-treated patients, the risk of delayed myelodysplasia or myeloid leukemia requires hematological follow-up. Monitor patients for second primary malignancies [see Adverse Reactions].

Cutaneous reactions: Localized erythema of the extremities with edema followed by desquamation has been observed. In case of severe skin toxicity, an adjustment in dosage is recommended [see Dosage and Administration]. The discontinuation rate due to skin toxicity was 1.6% (15/965) for metastatic breast-cancer patients. Among 92 breast-cancer patients premedicated with 3-day corticosteroids, there were no cases of severe skin toxicity reported and no patient discontinued docetaxel due to skin toxicity.

Severe cutaneous adverse reactions (SCARs) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP) have been reported in association with docetaxel treatment. Patients should be informed about the signs and symptoms of serious skin manifestations and monitored closely. Permanent treatment discontinuation should be considered in patients who experience SCARs.

Neurologic reactions: Severe neurosensory symptoms (e.g., paresthesia, dysesthesia, pain) were observed in 5.5% (53/965) of metastatic breast-cancer patients and resulted in treatment discontinuation in 6.1%. When these symptoms occur, dosage must be adjusted. If symptoms persist, treatment should be discontinued [see Dosage and Administration].

Patients who experienced neurotoxicity in clinical trials and for whom follow-up information on the complete resolution of the event was available had spontaneous reversal of symptoms with a median of 9 weeks from onset (range 0 to 106 weeks). Severe peripheral motor neuropathy, mainly manifested as distal extremity weakness, occurred in 4.4% (42/965).

Warnings and Precautions (cont.)

Eye disorders: Cystoid macular edema (CME) has been reported in patients treated with docetaxel. Patients with impaired vision should undergo prompt and comprehensive ophthalmologic examination. If CME is diagnosed, Beizray treatment should be discontinued and appropriate therapy initiated. Alternative non-taxane cancer treatment should be considered.

Asthenia: Severe asthenia has been reported in 14.9% (144/965) of metastatic breast-cancer patients but has led to treatment discontinuation in only 1.8%. Symptoms of fatigue and weakness may last a few days up to several weeks and may be associated with deterioration of performance status in patients with progressive disease.

Embryo-fetal toxicity: Based on findings from animal reproduction studies and its mechanism of action, Beizray can cause fetal harm when administered to a pregnant woman [see Clinical Pharmacology]. Available data from case reports and pharmacovigilance with docetaxel use in pregnant women are not sufficient to inform the drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal studies, administration of docetaxel to pregnant rats and rabbits during organogenesis caused embryo-fetal toxicities, including intrauterine mortality, at doses as low as 0.02 and 0.003 times the recommended human dose based on body-surface area, respectively.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to initiating Beizray. Advise females of reproductive potential to use effective contraception during treatment and for 2 months after the last dose of Beizray. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the last dose of Beizray [see Use in Specific Populations]

Alcohol Content: Cases of intoxication have been reported with some formulations of docetaxel due to the alcohol content. The alcohol content in a dose of Beizray Injection may affect the central nervous system and should be taken into account for patients in whom alcohol intake should be avoided or minimized. Consideration should be given to the alcohol content in Beizray Injection on the ability to drive or use machines immediately after the infusion. Each administration of Beizray Injection at 100 mg/m² delivers 4.0 g/m² of ethanol. For a patient with a BSA of 2.0 m², this would deliver 8.0 grams of ethanol [see Description]. Other docetaxel products may have a different amount of alcohol.

Tumor Lysis Syndrome: Tumor lysis syndrome has been reported with docetaxel [see Adverse Reactions]. Patients at risk of tumor lysis syndrome (e.g., with renal impairment, hyperuricemia, bulky tumor) should be closely monitored prior to initiating Beizray and periodically during treatment. Correction of dehydration and treatment of high uric acid levels are recommended prior to initiation of treatment.

Transmissible Infectious Agents: Beizray final infusion solution contains Albumin Human USP, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries a remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

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, also available at the QR code