

Nab-Xelpac

Nanoparticle albumin-bound Paclitaxel
for injectable suspension

Lyophilized Powder for IV Infusion

COMPOSITION

Nab-Xelpac Injection: Each vial contains Paclitaxel USP 100 mg (Nanoparticle albumin-bound).

DESCRIPTION

Nanoparticle albumin-bound paclitaxel is, a microtubule inhibitor, is an albumin-bound form of paclitaxel with a mean particle size of approximately 130 nanometers. Paclitaxel exists in the particles in a non-crystalline, amorphous state. Nanoparticle albumin-bound paclitaxel is supplied as a white to yellow, sterile, lyophilized powder for reconstitution with 20 mL of 0.9% Sodium Chloride Injection USP prior to intravenous infusion.

PHARMACOLOGICAL INFORMATION

Mechanism of Action

Nanoparticle albumin-bound paclitaxel is a microtubule inhibitor that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. Paclitaxel induces abnormal arrays or "bundles" of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

INDICATIONS AND USAGE

Nab-Xelpac is a microtubule inhibitor indicated for the treatment of:

- Metastatic Breast Cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

DOSAGE AND ADMINISTRATION

- Metastatic Breast Cancer: Recommended dosage of Nab-Xelpac is 260 mg/m² intravenously over 30 minutes every 3 weeks.
- Non-Small Cell Lung Cancer: Recommended dosage of Nab-Xelpac is 100 mg/m² intravenously over 30 minutes on Days 1, 8, and 15 of each 21-day cycle; carboplatin is given intravenously on Day 1 of each 21 day cycle immediately after Nab-Xelpac administration.
- Adenocarcinoma of the Pancreas: Recommended dosage of Nab-Xelpac is 125 mg/m² intravenously over 30-40 minutes on Days 1, 8 and 15 of each 28-day cycle; administer gemcitabine on Days 1, 8 and 15 of each 28-day cycle immediately after Nab-Xelpac.

No adjustment is necessary for patients with mild hepatic impairment. Withhold Nab-Xelpac if AST > 10 x ULN or bilirubin > 5 x ULN. Reduce starting dose in patients with moderate to severe hepatic impairment. Use caution when handling cytotoxic drugs. Closely monitor the infusion site for extravasation and infiltration. No premedication is required prior to administration.

DOSE REDUCTIONS

Dose reductions or discontinuation may be needed based on severe hematologic, neurologic, cutaneous, or gastrointestinal toxicities.

PREPARATION FOR ADMINISTRATION

Nab-Xelpac is supplied as a sterile lyophilized powder for reconstitution before use. AVOID ERRORS, READ ENTIRE PREPARATION INSTRUCTIONS PRIOR TO RECONSTITUTION.

1. Aseptically, reconstitute each vial by injecting 20 mL of 0.9% Sodium Chloride Injection, USP.
2. Slowly inject the 20 mL of 0.9% Sodium Chloride Injection, USP, over a minimum of 1 minute, using the sterile syringe to direct the solution flow onto the INSIDE WALL OF THE VIAL.
3. DO NOT INJECT the 0.9% Sodium Chloride Injection, USP, directly onto the lyophilized cake as this will result in foaming.
4. Once the injection is complete, allow the vial to sit for a minimum of 5 minutes to ensure proper wetting of the lyophilized cake/powder.
5. Gently swirl and/or invert the vial slowly for at least 2 minutes until complete dissolution of any cake/powder occurs. Avoid generation of foam.
6. If foaming or clumping occurs, stand solution for at least 15 minutes until foam subsides.

CONTRAINDICATIONS

Nab-Xelpac should not be used in patients who have baseline neutrophil counts of < 1,500 cells/mm³. Patients who experience a severe hypersensitivity reaction to Nab-Xelpac should not be rechallenged with the drug.

WARNINGS AND PRECAUTIONS

Nab-Xelpac causes myelosuppression. Monitor CBC and withhold and/or reduce the dose as needed. Sensory neuropathy occurs frequently and may require dose reduction or treatment interruption. Severe hypersensitivity reactions with fatal outcome have been reported. Do not re-challenge with this drug. Exposure and toxicity of paclitaxel can be increased in patients with hepatic impairment; therefore administer with caution. Nab-Xelpac contains albumin derived from human blood, which has a theoretical risk of viral transmission. Fetal harm may occur when administered to a pregnant woman. Advise women of childbearing potential to avoid becoming pregnant while receiving Nab-Xelpac. Advise men not to father a child while on Nab-Xelpac.

ADVERSE REACTIONS

The most common adverse reactions (≥ 20%) in metastatic breast cancer are alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, infections, and diarrhea. The most common adverse reactions (≥ 20%) in NSCLC when used in combination with carboplatin are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue.

DRUG INTERACTIONS

Use caution when concomitantly administering NAB-XELPAC with inhibitors or inducers of either CYP2C8 or CYP3A4.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category D.

There are no adequate and well-controlled studies in pregnant women using Nab-Xelpac. Based on its mechanism of action and findings in animals, Nab-Xelpac can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving Nab-Xelpac.

Nursing Mothers

It is not known whether paclitaxel is excreted in human milk. Paclitaxel and/or its metabolites were excreted into the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of Nab-Xelpac in pediatric patients have not been evaluated.

Geriatric Use

Of the 229 patients in the randomized study who received Nab-Paclitaxel for the treatment of metastatic breast cancer, 13% were at least 65 years of age and < 2% were 75 years or older. No toxicities occurred notably more frequently among patients who received Nab-Paclitaxel.

Of the 514 patients in the randomized study who received Nab-Paclitaxel and carboplatin for the first-line treatment of non-small cell lung cancer, 31% were 65 years or older and 3.5% were 75 years or older. Myelosuppression, peripheral neuropathy, and arthralgia were more frequent in patients 65 years or older compared to patients younger than 65 years old. No overall difference in effectiveness, as measured by response rates, was observed between patients 65 years or older compared to patients younger than 65 years old.

Patients with Hepatic Impairment

Because the exposure and toxicity of paclitaxel can be increased in patients with hepatic impairment, the administration of Nab-Xelpac should be performed with caution in patients with hepatic impairment

Patients with Renal Impairment

The use of Nab-Xelpac has not been studied in patients with renal impairment.

OVERDOSAGE

There is no known antidote for Nab-Xelpac overdose. The primary anticipated complications of overdose would consist of bone marrow suppression, sensory neurotoxicity, and mucositis.

PHARMACEUTICAL INFORMATION

Storage Conditions

Store the vial in original carton at 20°C-25°C, away from light. Store the reconstituted suspension at 2°C-8°C, away from light. Keep out of the reach of children. Use the reconstituted suspension within 8 hours. Discard any unused portion.

Handling and Disposal

Procedures for proper handling and disposal of anticancer drugs should be considered.

Presentation & Packaging

Nab-Xelpac Injection: Each box contains 1 vial of Nab-Xelpac injection (as lyophilized powder).

Manufactured By
 **BEACON**
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Mymensingh, Bangladesh

LF17201