**Paclitaxel Injection USP, 30 mg/5 mL (6 mg/mL), 100 mg/16.7 mL (6 mg/mL), and 300 mg/50 mL (6 mg/mL); Multiple-Dose Vials.**

| S.No. | Category | Question | Answer |
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| **Clinical Particulars** | | | |
| 1 | Use/Indication | What is the product indicated for? | • Paclitaxel Injection, USP is indicated as subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel Injection, USP is indicated in combination with cisplatin.<br>• Paclitaxel Injection, USP is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.<br>• Paclitaxel Injection, USP is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.<br>• Paclitaxel Injection, USP, in combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.<br>• Paclitaxel Injection, USP is indicated for the second-line treatment of AIDS-related Kaposi's sarcoma. |
| 2 | Dosage | What is the recommended dosage? | **DOSAGE AND ADMINISTRATION-ADULTS**<br>All patients should be premedicated prior to paclitaxel administration in order to prevent severe hypersensitivity reactions. Such premedication may consist of dexamethasone 20 mg PO administered approximately 12 and 6 hours before paclitaxel, diphenhydramine (or its equivalent) 50 mg I.V. 30 to 60 minutes prior to paclitaxel, and cimetidine (300 mg) or ranitidine (50 mg) I.V. 30 to 60 minutes before paclitaxel.<br><br>For patients with carcinoma of the ovary, the following regimens are recommended<br>• For previously untreated patients with carcinoma of the ovary, one of the following recommended regimens may be given every 3 weeks. In selecting the appropriate regimen, differences in toxicities should be considered<br>• In patients previously treated with chemotherapy for carcinoma of the ovary, paclitaxel has been used at several doses and schedules; however, the optimal regimen is not yet clear<br>For patients with carcinoma of the breast, the following regimens are recommended<br><br>• For the adjuvant treatment of node-positive breast cancer, the recommended regimen is paclitaxel, at a |

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| | | | dose of 175 mg/m intravenously over 3 hours every 3 weeks for 4 courses administered<br>• After failure of initial chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy, paclitaxel at a dose of 175 mg/m administered intravenously over 3 hours every 3 weeks has been shown to be effective.<br><br>**(For complete details, please refer to full Prescribing Information**) |
| 3 | Administration | Administration precautions | **<u>Precautions</u>**<br>Paclitaxel is a cytotoxic anticancer drug and, as with other potentially toxic compounds, caution should be exercised in handling paclitaxel. The use of gloves is recommended. If paclitaxel solution contacts the skin, wash the skin immediately and thoroughly with soap and water. If paclitaxel contacts mucous membranes, the membranes should be flushed thoroughly with water. |
| 4 | Administration | Reconstitution for intravenous and subcutaneous | • Use proper aseptic technique.<br>• Paclitaxel must be diluted prior to infusion. Paclitaxel should be diluted in 0.9% Sodium Chloride Injection, USP; 5% Dextrose Injection, USP; 5% Dextrose and 0.9% Sodium Chloride Injection, USP; or 5% Dextrose in Ringer's Injection to a final concentration of 0.3 to 1.2 mg/mL.<br>• The solutions are physically and chemically stable for up to 27 hours at ambient temperature (approximately 25C) and room lighting conditions. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.<br>**(For complete information, please refer to prescribing information)** |
| 5 | Administration | Use in Pediatric Population | The safety and effectiveness of paclitaxel in pediatric patients have not been established. |
| 6 | Administration | Use in Geriatric Population | • In most studies, severe myelosuppression was more frequent in elderly patients; in some studies, severe neuropathy was more common in elderly patients<br>• In a study of first line treatment of ovarian cancer, elderly patients had a lower median survival than younger patients, but no other efficacy parameters favored the younger group. |
| 7 | Side effects | What are the most common and possible side effects | severe stomach pain, severe diarrhea, ow red blood cell count (anemia) feeling weak or tired, hair loss, numbness, tingling, or burning in your hands or feet (neuropathy), joint and muscle pain, nausea and vomiting, hypersensitivity reaction - trouble breathing; sudden swelling of your face, lips, tongue,<br>throat, or trouble swallowing; hives (raised bumps) or rash, diarrhea, mouth or lip sores (mucositis), infections - if you have a fever (temperature above 100.4°F) or other sign of infection,<br>tell your healthcare provider right away, swelling of your hands, face, or feet, bleeding events, irritation at the injection site, low blood pressure (hypotension) |

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| 8 | Mechanism | Mechanism of Action | Paclitaxel is a novel ant microtubule agent that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing de polymerization. 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. In addition, paclitaxel induces abnormal arrays or “bundles” of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis. Following intravenous administration of paclitaxel, paclitaxel plasma concentrations declined in a biphasic manner. The initial rapid decline represents distribution to the peripheral compartment and elimination of the drug. The later phase is due, in part, to a relatively slow efflux of paclitaxel from the peripheral compartment |
| 9 | Warning | Black Box Warning | Paclitaxel consist of black box warning. |
| 10 | Warning | Warnings and precautions | • Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in 2 to 4% of patients receiving paclitaxel in clinical trials.<br>• All patients should be pretreated with corticosteroids, diphenhydramine, and H antagonists.<br>• Dose limitations and monitoring should be there for the conditions like Bone marrow suppression, decreased baseline neutrophil counts<br>• Frequent monitoring of blood counts should be instituted during paclitaxel treatment. |
| 11 | Lactation | Use in Lactation | If patient is breast-feeding or plan to breast-feed, she should tell her healthcare provider before receiving Paclitaxel. Patient and Healthcare provider shall decide if patient will receive paclitaxel or continue to breast-feed. |
| 12 | Pregnancy | Use in Pregnancy | Paclitaxel can harm unborn baby. Patient should talk to healthcare provider if pregnant or planning to become pregnant. |
| 13 | Storage | What are the storage conditions? | Store the vials in original cartons between 20 to 25 ° C (68 to 77 **°F**) [See USP Controlled Room Temperature]. Retain in the original package to protect from light. |
| 14 | Dispensing | How to Dispense? | As prescribed by physician. |
| 15 | Contraindication | What are the contraindications of (medication)? | Paclitaxel is contraindicated in patients who have a history of hypersensitivity reactions to Paclitaxel or other drugs formulated in polyoxyl 35 castor oil. Paclitaxel should not be used in patients with solid tumors who have baseline neutrophil counts of less than 1,000 cells/mm3. |
| **Pharmaceutical Particulars** | | | |
| 16 | Pharmaceutical Form | How Supplied | Paclitaxel Injection, USP (6 mg/mL) is available as follows: b c ○ ○ ○ NDC 72205-061-01 30 mg/5 mL multidose vial individually packaged in a carton.<br>• NDC 72205-062-01 100 mg/16.7 mL multidose vial individually packaged in a carton.<br>• NDC 72205-063-01 300 mg/50 mL multidose vial individually packaged in a carton. |

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| 17 | Ingredients | Active and Inactive | **Active ingredient:** Paclitaxel<br>**Inactive ingredients:** Polyoxyl 35 castor oil, castor oil, citric acid monohydrate. |
| **Allergens** | | | |
| 18 | Ingredients | Does it contain Gluten? | No |
| 19 | Ingredients | Does it contain alcohol? | Paclitaxel API contains Methanol NMT 3000 PPM Dehydrated alcohol used as excipient. |
| 20 | Ingredients | Does it contain dyes? | No |
| 21 | Ingredients | Does it contain Lactose? | No |
| 22 | Ingredients | Does it contain Nuts? | No |
| 23 | Ingredients | Does it contain Preservatives? | No |
| 24 | Ingredients | Does it contain Soy products? | No |
| 25 | Ingredients | Does it contain peanut? | No |
| **Miscellaneous** | | | |
| 26 | Miscellaneous | May I know the product availability? | Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products. |
| 27 | Miscellaneous | May I know about return, refunds and reimbursement? | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500 |
| 28 | Miscellaneous | Do you have any patient's assistance program? | Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company |
| 29 | Miscellaneous | Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation? | Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products |
| 30 | Miscellaneous | May I know where is this product manufactured? | **Manufactured by**:<br>MSN Laboratories Private Limited<br>Telangana – 509 228, INDIA<br><br>**Distributed by**:<br>Novadoz Pharmaceuticals LLC<br>Piscataway, NJ 08854-3714 |