Gemcitabine (200mg, 1g & 2g) Pack Insert- APP-US (Baddi-II)

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Full prescribing information:

- Full prescribing information is provided in the document. It includes various sections such as description, clinical pharmacology, contraindications, warnings and precautions, adverse reactions, dosage and administration, precautions for patient use, and patient counseling information. The information is structured in a clear and organized manner, making it easy to navigate and find specific sections.

- The document also contains tables and lists, such as the table of adverse reactions in patients receiving gemcitabine for injection, which provides a comprehensive overview of potential side effects. These elements help in understanding the medication's profile and potential risks.

- The appendices (Appendix I and Appendix II) seem to contain additional data or references related to the product. However, without further context, it's challenging to determine their exact content or relevance.

Overall, the document is a comprehensive resource for clinicians and healthcare providers, offering detailed information on the use, effects, and precautions associated with gemcitabine. This rich information is essential for ensuring safe and effective usage in clinical practice.
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8.3 Nursing Mothers

No differences in the incidence of laboratory and non-laboratory events were reported following or in more doses of gemcitabine. Before birth to or in breast feeding, it is not known whether gemcitabine is excreted in breast milk, or if it could affect the nursing infant. Because many drugs are excreted in human milk, caution should be exercised when gemcitabine is administered to a nursing mother.

8.4 Pediatric Use

In addition to blood product transfusions as listed in Table 8, patients with refractory leukemia and determined that the maximum tolerated dose was 9 mg/m²/30 minute infusion of radiolabeled drug. Within one (1) week, 92% to 98% of drugs were recovered from blood plasma. Within one (1) week, 92% to 98% of drugs were recovered from blood plasma.

13 NONCLINICAL TOXICOLOGY

Clinical signs of peripheral vasculitis and gangrene have been reported very rarely in patients receiving gemcitabine alone or in combination with other pyrimidine and purine analogs. Bone marrow depression has been reported very rarely.

Dose

Gemcitabine is a nucleoside metabolic inhibitor that exhibits tumor cell cytotoxicity through inhibition of DNA synthesis. The active metabolite, gemcitabine triphosphate, can be extracted from peripheral blood mononuclear cells. The concentration of gemcitabine triphosphate in mononuclear cells ranges from 1.7 to 19.4 nM/m² in plasma. The elimination of gemcitabine was significantly influenced by duration of infusion and gender.

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1.1 Mechanism of Action

The addition of gemcitabine to cisplatin resulted in statistically significant improvements in response rates and progression-free survival compared to cisplatin alone. As an example, Table 8 shows that the 23% rate of response to carboplatin alone increased to 47% with the addition of gemcitabine. The 6.7% rate of progression-free survival for patients treated with carboplatin alone increased to 23.2% with the addition of gemcitabine. These results suggest that the addition of gemcitabine to cisplatin may further improve the efficacy of cisplatin in the treatment of patients with advanced ovarian cancer.

14.2 Non-Small Cell Lung Cancer (NSCLC)

The addition of gemcitabine to paclitaxel resulted in statistically significant improvements in response rates and progression-free survival compared to paclitaxel alone. As an example, Table 8 shows that the 40% rate of response to paclitaxel alone increased to 54% with the addition of gemcitabine. The 37.2% rate of progression-free survival for patients treated with paclitaxel alone increased to 43.4% with the addition of gemcitabine. These results suggest that the addition of gemcitabine to paclitaxel may further improve the efficacy of paclitaxel in the treatment of patients with advanced NSCLC.

8.2.1 Pregnancy

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