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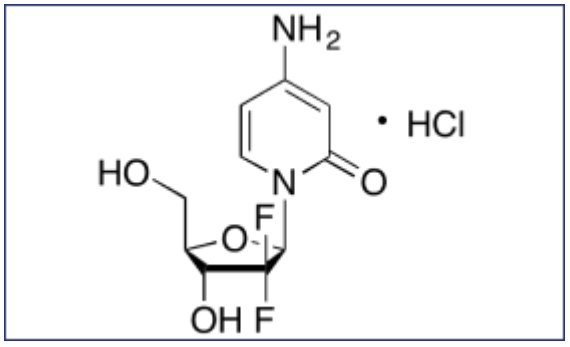
Gemcitabine hydrochloride

Description

Cytotoxic drug, antimetabolite from the group of pyrimidine antagonists.

Chemical formula



Pharmachologic effect

The drug exhibits cyclo-specificity, acting on cells in the S and G1 / S phases. Gemcitabine is metabolized inside the cell by the action of nucleoside kinases to form active diphosphate and triphosphate nucleosides. Diphosphate nucleosides inhibit ribonucleotide reductase, which acts as the only catalyst for reactions leading to the formation of deoxynucleoside triphosphates required for DNA synthesis. Triphosphate nucleosides actively compete with deoxycytidine triphosphate for incorporation into DNA and RNA molecules. After the incorporation of the intracellular metabolites of gemcitabine into the DNA chain, another additional nucleotide is added to its growing strands. These events result in complete inhibition of further DNA synthesis and programmed cell lysis, known as apoptosis.

Indications

- bladder cancer;
- locally advanced or metastatic non-small cell lung cancer (as first-line drug as monotherapy or in combination with cisplatin);
- pancreatic cancer (locally advanced or metastatic adenocarcinoma of the pancreas).

Dosage regimen

- In bladder cancer with monotherapy, gemcitabine is administered intravenously at a dose of 1.25 g / m2 for 30 minutes on days 1, 8 and 15 of each 28-day cycle. In combination with

cisplatin, gemcitabine is administered at a dose of 1 g / m2 on days 1, 8 and 15 of each 28-day cycle. Cisplatin is administered at a dose of 70 mg / m2 on 1 (immediately after gemcitabine) or 2 days of each 28-day cycle.

- In non-small cell lung cancer with monotherapy, gemcitabine is administered intravenously at a dose of 1 g / m2 for 30 minutes, 1 time per week for 3 weeks, followed by a weekly break. Thereafter, repeat similar 4-week cycles. In combination with cisplatin, gemcitabine is administered intravenously at a dose of 1.25 g / m2 on days 1 and 8 of each 21-day cycle or at a dose of 1 g / m2 on days 1, 8, and 15 of each 28-day cycle.
- In pancreatic cancer with monotherapy, gemcitabine is administered intravenously at a dose of 1 g / m2 for 30 minutes, 1 time per week for 7 weeks, followed by a weekly break. In subsequent cycles, the injection is performed once a week for 3 weeks, followed by a weekly break.

In patients receiving gemcitabine, the number of platelets, leukocytes and granulocytes in the blood should be monitored before each administration. In case of development of hematological toxicity, the dose of gemcitabine can be reduced or postponed.

To identify non-hematological toxicity, it is necessary to conduct regular examination of the patient and monitor the functions of the liver and kidneys. Depending on the degree of toxicity, the dose can be reduced during each cycle or at the beginning of a new cycle in steps. The decision to postpone the next administration of the drug should be based on the doctor's clinical assessment of the dynamics of toxic manifestations. In elderly patients, there is no data to suggest the need for dose adjustment, although the clearance of gemcitabine and T1 / 2 change with age.

Solution preparation rules

To prepare gemcitabine solution, use only 0,9% sodium chloride solution without preservatives. To dissolve 200 mg of the drug, at least 5 ml of 0,9% sodium chloride solution for injection is added to the vial, and at least 25 ml is added to dissolve 1 g of the drug. The vials are shaken until the lyophilized powder is completely dissolved. The maximum concentration of gemcitabine should not exceed 40 mg / ml. In solutions with a concentration of gemcitabine more than 40 mg / ml, incomplete dissolution is possible. The prepared solution of gemcitabine, containing the appropriate dose of the drug, is diluted with a sufficient amount of 0,9% sodium chloride solution for injection before administration for intravenous infusion for 30 minutes. Before parenteral administration, a visual control of the prepared solution for the presence of mechanical impurities and color changes is required.