For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

FLUDARA®

Fludarabine phosphate Powder for solution for Injection or Infusion.

THERAPEUTIC CATEGORY
Anti-cancer

COMPOSITION
Fludara® Injection: Each vial contains Fludarabine phosphate 50 mg.

THERAPEUTIC INDICATIONS
Fludara is indicated for the treatment of patients with B-cell chronic lymphocytic leukemia (CLL) who have not responded to at least one standard alkylating-agent containing regimen.

DOSAGE AND ADMINISTRATION
Fludara Injection: For full reconstitution and administration details refer full prescribing information. Adults – IV administration only. Recommended dose is 25 mg /m² body surface given daily for 5 consecutive days every 28 days.
Fludara should be administered up to the achievement of best response (complete or partial remission, usually 6 cycles) and then the drug should be discontinued. Children - The safety and efficacy not established. Reduced kidney function – Dosage adjustment necessary. If creatinine clearance (CrCl) is between 30 and 70 ml/min, the dose should be reduced by up to 50 % and close hematological monitoring should be used to assess toxicity.

SAFETY-RELATED INFORMATION
Contraindications: In patients who are hypersensitive to this drug or its components, in renally impaired patients with creatinine clearance < 30 ml/min, and in patients with decompensated haemolytic anemia.
Precautions & Warnings: *Neurotoxicity:* When used at high doses in clinical studies, Fludara was associated with severe neurologic effects, including blindness, coma and death. In patients treated at doses in the range of the dose recommended for chronic lymphocytic leukaemia, severe CNS toxicity occurred rarely or uncommonly.
Whenever leukoencephalopathy (LE), acute toxic leukoencephalopathy (ATL) or reversible posterior leukoencephalopathy syndrome (RPLS). is suspected, fludarabine treatment should be stopped. Patients should be monitored and should undergo brain imaging, preferably utilizing MRI. If the diagnosis is confirmed, fludarabine therapy should be permanently discontinued.
Impaired state of health: Use with caution and after careful risk/ benefit consideration.
Myelosuppression: Severe bone marrow suppression, notably anemia, thrombocytopenia and neutropenia, has been reported. Careful haematologic monitoring is required. Several instances of trilineage bone marrow hypoplasia or aplasia resulting in pancytopenia, sometimes resulting in death reported in adult patients.
Disease progression: Disease progression and transformation have been commonly reported in CLL patients.
Transfusion associated graft-versus-host disease: Observed after transfusion of non-irradiated blood in Fludara treated patients. Fatal outcome as a consequence of this disease has been reported with a high frequency.
Skin cancer: The worsening or flare up of preexisting skin cancer lesions as well as new onset of skin cancer has been reported in patients during or after therapy.
Tumor lysis syndrome: Reported in patients with large tumor burdens, precaution should be taken in those patients at risk of developing this complication.
Autoimmune phenomena: Irrespective of any previous history of autoimmune processes or Coombs test status, life-threatening and sometimes fatal autoimmune phenomena have been reported to occur during or after treatment. Patients to be closely monitored for signs of hemolysis. Discontinuation of therapy is recommended in such cases.
The elderly: There are limited data in elderly persons (> 75 years), caution should be exercised.
Vaccination: Vaccination with live vaccines should be avoided during or after treatment.
Pregnancy & Lactation: Fludara may cause fetal harm when administered to pregnant females. Therefore, Fludara must not be used during pregnancy. It is not known whether fludarabine phosphate is excreted in human milk. Because of the potential for adverse reactions in nursing infants, breast feeding must be discontinued for the duration of Fludara therapy

Adverse Reactions: Very common (≥1/10) - Infections/ Opportunistic infections (like latent viral reactivation, e.g. Herpes zoster virus Epstein- Barr-virus, Progressive multifocal leucoencephalopathy), pneumonia, neutropenia, anemia, thrombocytopenia, cough, nausea, vomiting, diarrhoea, fever, fatigue and weakness. Common (≥ 1/100 to < 1/10) – Myelodysplastic syndrome and Acute myeloid leukaemia (mainly associated with prior, concomitant or subsequent treatment with alkylating agents, topoisomerase inhibitors or irradiation), Myelosuppression, Anorexia, Neuropathy peripheral, Visual disturbance, Stomatitis, Rash, Chills, Malaise, Edema, Mucositis

For full prescribing information please contact: Sanofi Healthcare India Private Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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