

INDICATION and IMPORTANT SAFETY INFORMATION for DACOGEN[®] (decitabine) for injection

INDICATION:

DACOGEN is a prescription medicine indicated for treatment of patients with myelodysplastic syndromes (MDS), including:

- Previously treated and untreated MDS
- De novo (cause unknown) and secondary (treatment-related) MDS:
 - All French-American-British (FAB) subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia)
 - Intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System (IPSS) groups.

IMPORTANT SAFETY INFORMATION:

- **Treatment with DACOGEN is associated with serious, sometimes fatal, blood disorders including:**
 - fewer white blood cells (neutropenia and leukopenia), platelets (thrombocytopenia), and/or red blood cells (anemia)
 - fever associated with low white blood cell counts (febrile neutropenia)
 - bone marrow suppression
 - infections

Your doctor will test and monitor your blood cells before and during treatment with DACOGEN. Your doctor may prescribe medicine to help manage your blood cell counts and/or medicines to prevent or treat infections. Your doctor may need to delay your treatment and/or reduce your dose if you experience certain side effects. Patients should monitor and report any symptoms or fever to their doctor as soon as possible

- **Harm to a fetus when administered to a pregnant woman:** Women of childbearing potential and men with female partners of childbearing potential should use effective contraception and avoid pregnancy while taking DACOGEN
- **Other common side effects including:**

- feeling tired (fatigue)	- reddish or purplish spots (petechiae)
- fever (pyrexia)	- constipation
- nausea	- diarrhea
- cough	- high blood sugar (hyperglycemia)
- **DACOGEN should be used with caution if you have kidney or liver problems**

You are encouraged to report side effects of DACOGEN[®] (decitabine), please contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA1088 (www.fda.gov/medwatch).

Please see [FULL PRESCRIBING INFORMATION](#).