Generic Name:
Dasatinib
Trade Name:
Sprycel
Company:
Bristol-Myers Squibb
Notes:

Dasatinib may increase the risk of of pulmonary arterial hypertension (PAH), according to a safety alert released by FDA today. Since the drug's approval in June 2006, a total of 12 cases of PAH have been identified through the manufacturer?s global pharmacovigilance program and confirmed using right heart catheterization. Patients developed PAH after taking dasatinib for various amounts of time, including use for more than 1 year. No fatalities from the condition have been reported, and in some cases, improvements in hemodynamic and clinical parameters were observed following discontinuation of dasatinib.

Information about this risk has been added to the Warnings and Precautions section of the labeling. According to the agency, health care providers should evaluate patients for signs and symptoms of underlying cardiopulmonary disease before starting dasatinib and during treatment. If PAH is confirmed, the drug should be permanently discontinued. In addition, patients should be educated on the symptoms of PAH: shortness of breath, fatigue, and swelling of the ankles and legs. Patients who develop these symptoms should notify their health care professional immediately.

Dasatinib is indicated for the treatment of adults with Philadelphia chromosome?positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy, for the treatment of adults with newly diagnosed Philadelphia chromosome?positive chronic myeloid leukemia (CML) in chronic phase, and for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome-positive CML with resistance or intolerance to prior therapy.

Medication Monitor Categories:
Alerts and Recalls