MedWatch The FDA Safety Information and Adverse Event Reporting Program

Sprycel (dasatinib): Drug Safety Communication – Risk of Pulmonary Arterial Hypertension

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FDA 公告 Sprycel (dasatinib)可能會增加肺動脈高壓（pulmonary arterial hypertension, PAH）的機率，這種情況罕見但嚴重。肺動脈高壓（PAH）的症狀包含呼吸短促、疲倦、水腫（例如腿部與腳踝）。根據案例報告，患者開始使用 Sprycel 後出現肺動脈高壓（PAH），其中包含使用 Sprycel 一年以上的患者。相關的訊息會新增到 Sprycel 仿單。

病患在使用 Sprycel (dasatinib)之前和使用期間，應被評估是否有心肺疾病的症狀。如果證實肺動脈高壓（PAH），則應永久停用 Sprycel (dasatinib)。

Sprycel (dasatinib): Drug Safety Communication – Risk of Pulmonary Arterial Hypertension

UDIENCE: Hematology, Oncology

ISSUE: FDA notified healthcare professionals that Sprycel (dasatinib) may increase the risk of a rare but serious condition in which there is abnormally high blood pressure in the arteries of the lungs (pulmonary arterial hypertension [PAH]). Symptoms of PAH may include shortness of breath, fatigue, and swelling of the body (such as the ankles and legs). In reported cases, patients developed PAH after starting Sprycel, including after more than one year of treatment.Information about this risk has been added to the Warnings and Precautions section of the Sprycel drug label.

BACKGROUND: Sprycel (dasatinib) is used to treat certain adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (CML) or acute lymphoblastic leukemia (ALL).

RECOMMENDATION: Healthcare professionals should evaluate patients for signs and symptoms of underlying cardiopulmonary disease prior to starting Sprycel and also during treatment. If PAH is confirmed, Sprycel should be permanently discontinued.