Consumer Update Feb 2022

Pirfenidone Risks of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).

EDA performs label update to include the following:

Special warnings and precautions for use
Severe skin reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported post-marketing in association with Esbriet treatment. If signs and symptoms suggestive of these reactions appear, Esbriet should be withdrawn immediately. If the patient has developed SJS or TEN with the use of Esbriet, treatment with Esbriet must not be restarted and should be permanently discontinued.
Undesirable effects
Not Known Stevens-Johnson syndrome1; toxic epidermal necrolysis.

Background:

Therapeutic indications
Pirfenidone is indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).
method of administration
Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of IPF.
Adults
Upon initiating treatment, the dose should be titrated to the recommended daily dose of nine capsules per day over a 14-day period as follows:
- Days 1 to 7: one capsule, three times a day (801 mg/day)
- Days 8 to 14: two capsules, three times a day (1602 mg/day)
- Day 15 onward: three capsules, three times a day (2403 mg/day)

The recommended maintenance daily dose is three 267 mg capsules three times a day with food for a total of 2403 mg/day.
Doses above 2403 mg/day are not recommended for any patient

References: *EMA (Click here)*