Pfizer
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King Abdelaziz Road
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Saudi Arabia

Date 21-Dec-2014

Dear Health Care Professional,

Subject: Association of Sutent® (sunitinib) with Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN).

Summary

Pfizer in collaboration with Saudi Food and drug Authority would like to inform you with updates related to the label of **Sunitinib (SUTENT®)**.

- **Cases of Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), including fatal cases, have been very rarely reported, mostly in the post-marketing setting, in patients who have used Sutent®.**
- **If signs or symptoms of TEN or SJS are present, Sutent® treatment should be discontinued. If the diagnosis of SJS or TEN is confirmed, treatment must not be restarted.**
- **Patients should be advised that depigmentation of the hair or skin may also occur during treatment with Sunitinib.**

Therapeutic Indication

In Saudi Arabia, Sunitinib (SUTENT®) is indicated for the following:

Gastrointestinal stromal tumor (GIST), Sunitinib (SUTENT®) is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.
Metastatic renal cell carcinoma (MRCC), Sunitinib (SUTENT®) is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.
Pancreatic NeuroEndocrine Tumours (pNET), Sunitinib (SUTENT®) is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults, experience with **Sunitinib (SUTENT®)** as first-line treatment is limited.

Further information on the safety concern

The special warning and precautions for use section in the label now has been updated as following:

Skin and tissue disorders:

- Severe cutaneous reactions have been reported, including cases of erythema multiforme (EM) and cases suggestive of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some of which were fatal. If signs or symptoms of SJS,

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TEN, or EM (e.g. progressive skin rash often with blisters or mucosal lesions) are present, Sunitinib treatment should be discontinued. If the diagnosis of SJS or TEN is confirmed, treatment must not be re-started. In some cases of suspected EM, patients tolerated the reintroduction of Sunitinib therapy at a lower dose after resolution of the reaction; some of these patients also received concomitant treatment with corticosteroids or antihistamines.

- Skin discolouration, possibly due to the active substance colour (yellow), is a very common adverse reaction occurring in approximately 30% of patients. Patients should be advised that depigmentation of the hair or skin may also occur during treatment with Sunitinib. Other possible dermatologic effects may include dryness, thickness or cracking of the skin, blisters, or occasional rash on the palms of the hands and soles of the feet.

Pfizer is committed to ensuring that **Sunitinib (SUTENT®)** is used safely and effectively and to providing you with the most current product information.

The information in this letter has been approved by the Saudi Food and Drug Authority.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

The National Pharmacovigilance & Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

Or

The Pharmacovigilance department in Pfizer:

- Email: SAU.AEReporting@Pfizer.com
- Fax: 012 22 93692

Yours sincerely,

Pfizer Country Medical Director

Pfizer Country Regulatory Lead

Full prescribing information is available upon request