

Adopted key elements for SmPC/PL regarding Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis for “high risk” drugs (for systemic use) allopurinol, carbamazepine, lamotrigine, phenobarbital, phenytoin, sulfamethoxazol, sulfasalazine, sulfadiazine, sulfafurazole, sulfadoxine, meloxicam, piroxicam, tenoxicam (and nevirapine centrally authorised product)

Final SmPC and PL wording agreed by the PhVWP in September 2011

*Doc.Ref.: CMDh/PhVWP/036/2011
October 2011*

SUMMARY OF PRODUCT CHARACTERISTICS

Section 4.4

- Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with the use of <medicine>.
- Patients should be advised of the signs and symptoms and monitored closely for skin reactions. The highest risk for occurrence of SJS or TEN is within the first weeks of treatment. (Adoption to individual drug if such data are available)
- If symptoms or signs of SJS or TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present, <medicine> treatment should be discontinued.
- The best results in managing SJS and TEN come from early diagnosis and immediate discontinuation of any suspect drug. Early withdrawal is associated with a better prognosis.
- If the patient has developed SJS or TEN with the use of <medicine>, <medicine> must not be re-started in this patient at any time.

Section 4.8

Severe cutaneous adverse reactions (SCARs): Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported (see section 4.4).

Frequency: very rare

(If robust frequency data are available for a particular drug, the frequency may be assigned based on these data).

PACKAGE LEAFLET

Section 2

-Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of <medicine>, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

- Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

- These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

- The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

(Adoption to individual drug if such data are available)

- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of <medicine>, you must not be re-started on <medicine> at any time.

Choice between these two alternatives depending on the existing information:

- If you develop a rash or these skin symptoms, stop taking <medicine>, seek urgent advice from a doctor and tell him that you are taking this medicine.

[For antiepileptics this sentence can be completed with a warning on danger of epileptic seizure due to drug withdrawal.]

or

-If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

Section 4

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

Frequency: very rare

(If robust frequency data are available for a particular drug, the frequency may be assigned based on these data).