

Carbamazepine related Stevens-Johnson Syndrome and association with HLA-B*1502

Final SPC and PIL wording agreed by PhVWP July 2008

Summary of Product Characteristics

For Section 4.2:

“Before deciding to initiate treatment, patients of Han Chinese and Thai origin should whenever possible be screened for HLA-B*1502 as this allele strongly predicts the risk of severe carbamazepine-associated SJS (see section 4.4)”

For Section 4.4:

“HLA-B*1502 in individuals of Han Chinese and Thai origin has been shown to be strongly associated with the risk of developing the severe cutaneous reactions known as Stevens-Johnson syndrome (SJS) when treated with carbamazepine. Whenever possible, these individuals should be screened for this allele before starting treatment with carbamazepine. If these individuals test positive, carbamazepine should not be started unless there is no other therapeutic option. Tested patients who are found to be negative for HLA-B*1502 have a low risk of SJS, although the reactions may still very rarely occur.

It is not definitely known whether all individuals of south east-Asian ancestry are at risk due to lack of data.

The allele HLA-B*1502 has been shown not to be associated to SJS in the Caucasian population.”

Package Leaflet

Under “Before taking your medicine” or “Take special care with [PRODUCT NAME]” addition of the following:

“Serious skin side effects can rarely occur during treatment with [PRODUCT NAME]. This risk can be predicted with a blood sample in people of Chinese and Thai origin. Discuss this with your doctor before taking [PRODUCT NAME] if you are of such origin.”