

**Phenytoin-related Stevens-Johnson Syndrome (SJS)
and association with HLA-B*1502
allele in individuals of Thai or Han Chinese origin**

Final SPC and PL wording agreed by the PhVWP in November 2009

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SUMMARY OF PRODUCT CHARACTERISTICS

Phenytoin (for oral administration)

Section 4.4

- HLA-B*1502 may be associated with an increased risk of developing Stevens-Johnson syndrome (SJS) in individuals of Thai and Han Chinese origin when treated with phenytoin. If these patients are known to be positive for HLA-B*1502, the use of phenytoin should only be considered if the benefits are thought to exceed risks.
- In the Caucasian and Japanese population, the frequency of the HLA-B*1502 allele is extremely low, and thus it is not possible at present to conclude on risk association. Adequate information about risk association in other ethnicities is currently not available.

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 may be associated with a variant in genes in a subject with Chinese or Thai origin. If you are of such origin and have been tested previously carrying this genetic variant (HLA-B*1502), discuss this with your doctor before taking [PRODUCT NAME].”*

No SPC change is recommended for Fosphenytoin or iv phenytoin

- *As far as fosphenytoin is concerned, as it is only used in emergency situation for one or two doses, the risks are considered negligible, so the same wording is not appropriate as per phenytoin.*
- *Based on the same reasoning, the same wording is not recommended for iv phenytoin.*