

OCTOBER 2014

New SPC and PIL for Diabact® UBT.

For your information, Kibion has submitted variations to all concerned EU-countries for an update of the SPC and PIL in accordance with new templates for the labeling and also new demands to add national information regarding "patient reporting of adverse events". Approval was granted in the beginning of October.

There are no product changes and no changes that will affect the quality, safety or efficacy of the product.

The new Approved English Master SPC and PIL you can find on the Kibion web in the usual place under Distributor login.

For the countries outside of EU which use the English Master as a template please check with your national MOH if any variation is needed.

Hopefully, you do not have to submit any variation as there are no product changes.

Best regards
KIBION AB