

Fluticasone Propionate

Recommendations:

- **Amendments to the Product Information**

During the assessment of the information in the PSUR the following issue was considered:
Epistaxis

A review of the data held by the company supports the addition of Epistaxis to the SPC. This is based on a number of reports including reports with positive rechallenge information for which there were no confounding factors.

It has been agreed that the following amendments to the Product Information are required:

SmPC wording

Section 4.8

Frequency unknown: epistaxis