

May 8, 2003

Seroxat 20mg Tablets, 30mg Tablets, Liquid (PA 49/50/1-3)

GlaxoSmithKline Pharmaceuticals

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Dear Doctor,

GSK would like to take this opportunity to inform you of forthcoming changes to the Patient Information Leaflet for Seroxat which will be available in packs on the market within the next 3 months. To facilitate any patient queries you may receive in the interim given the increased media scrutiny of SSRIs and symptoms experienced when stopping treatment, we would like to clarify the changes to the wording of the new Patient Information Leaflet, which has been approved by the Irish Medicines Board.

Under the section titled "How to take your tablets", GSK has removed the statement that reads "Remember that you cannot become addicted to 'Seroxat'." The company maintains that 'Seroxat' is not addictive, but feedback from patients has indicated that this statement, while valid, causes confusion and may suggest to patients that 'Seroxat' treatment can be stopped abruptly. In addition the following statement will now be included:

"Stopping treatment

DO NOT stop treatment with 'Seroxat' until told to do so by the doctor. Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with 'Seroxat', especially if this is done suddenly, you may experience symptoms including dizziness, sleep disturbances (strange dreams, inability to sleep), unusual sensations such as pins and needles, burning, apparent electric shocks, feeling nauseous, nervousness, agitation/restlessness or sweating. For the majority of people, these symptoms disappear without any treatment."

GSK will ensure that stock containing the new Patient Information Leaflet will be available within the required 3-month timeframe. This leaflet is also available on the IMB website, www.imb.ie.

We are providing you with this update as we appreciate that you are an important source of information for patients. GSK wish to emphasise that this new information does not change the overall product profile of 'Seroxat'.

Please do not hesitate to contact our Medical Information Department on freephone 1800 244 255 if you have any queries.

Yours sincerely,

Martina Dempsey

Director of Medical & Regulatory Affairs

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