

Venlafaxine Questions and Answers

1. What is venlafaxine?

Venlafaxine is an anti-depressant, belonging to a class of drugs known as serotonin noradrenaline reuptake inhibitors.

The conventional release form of venlafaxine (Efexor tablets) has been licensed for the treatment of depression since 1994 and the modified release form, Efexor XL (capsules), was introduced in 1997. The 'Efexor' brand is for the treatment of major depressive disorder (including depression accompanied by anxiety). The 'XL' brand is additionally licensed for the treatment of generalised anxiety disorder (GAD).

2. What is the new advice?

The new prescribing advice relates to:

- The need for specialist supervision in those severely depressed or hospitalised patients who need doses of 300mg daily or more
- Cardiac contra-indications are more targeted towards high risk groups.
- As previously, patients with uncontrolled hypertension should not take venlafaxine, and blood pressure monitoring is recommended for all patients
- Updated advice on possible drug interactions

3. How are prescribers being informed?

Prescribers are being informed through a letter from the Chairman of the Commission on Human Medicines (CHM) further communications from the manufacturer/marketing authorisation holder, and in updated product information.

4. How are patients being informed – and what should they do?

New patients will be informed through discussion with their doctor, and through an updated patient information leaflet, which incorporates all the new advice – and has a newly introduced 'headlines' section, to emphasise the most important points.

Patients already taking venlafaxine should discuss their treatment with their doctor at their routine appointment to see their doctor. For most patients, no changes to their treatment will be needed.

It is very important that patients do not stop treatment abruptly, and only reduce or change their venlafaxine dosage after discussion with their doctor. Sudden reductions in dosage can lead to withdrawal side effects.

5. Why is this being announced now?

This advice is being announced now, as it marks the conclusion of a long-running MHRA review into all the latest safety evidence relating to venlafaxine – and particularly the risks associated with venlafaxine overdose.

6. What evidence has been considered?

The MHRA review has re-examined previous safety evidence reviewed by the Committee on Safety of Medicines and Medicines Commission in 2005-5, as well as looking at new epidemiological data, published literature and information from the Yellow Card reporting scheme for suspected adverse drug reactions.

7. Why was the review undertaken?

The review was undertaken in the light of new evidence, and following an appeal by the Marketing Authorisation (MA) holder relating to previous prescribing advice from the Committee on Safety of Medicines.

8. What about other anti-depressants – is there any new advice for them?

The MHRA continually monitors the safety of all medicines – including all types of antidepressant. No new advice is being announced in relation to other antidepressants on this occasion.