Direct Healthcare Professional Communication

Venlafaxine hydrochloride – ViePax XL 150 mg prolonged-release tablets – changes including tablet appearance and formulation

14 June 2021

Dear Healthcare professional,

Dexcel Pharma Limited in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- The tablet formulation and appearance of ViePax XL 150 mg prolonged-release tablets (venlafaxine hydrochloride) is changing.
- The current capsule shaped coated tablets will be replaced with smaller round coated tablets.
- Both the capsule shaped and new round tablets are bioequivalent to the reference product.
- The new round tablets contain the same quantity of active substance and the same prolonged-release mechanism; the change relates to the shape, appearance and blend of excipients.
- Patients may be reassured that no changes to the safety and efficacy of this product are anticipated following this manufacturing change.

Background on the safety concern

ViePax XL is a prolonged-release venlafaxine tablet indicated for the treatment of anxiety disorders and the treatment and prevention of major depressive episodes.

The ViePax XL 150 mg prolonged-release tablets were formerly white convex capsule shaped coated tablets manufactured under product licence 14017/0119. The tablets are changing to 11 mm diameter white to off white, mottled round coated tablets manufactured under product licence 14017/0283 (summarised below). The new tablets are smaller and round to aid swallowing. The tablets are manufactured to produce the same prolonged-release mechanism where an extended-release coating adhered to a matrix core is used to deliver venlafaxine at a controlled rate for once daily dosing. There are some changes to the quantity and types of excipients used in the manufacture of the new tablets and this is highlighted by a 'new formulation' flash on the new product carton. There are no changes to the therapeutic indications, posology and method of administration, storage conditions or shelf life. There is no anticipated change in therapeutic effect.

Product Comparison	
Current formulation marketed under PL 14017/0119 ViePax XL 150 mg prolonged-release tablet	**New formulation marketed under PL 14017/0283 ViePax XL Dexcel 150 mg prolonged-release tablet**
Tablet Appearance	
White convex capsule shaped coated tablets	11 mm diameter white to off white, mottled round coated tablets

Dexcel Pharma Ltd
7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, Northamptonshire, NN11 8PB, United Kingdom
Tel: +44 (0)1327 312266 Fax: +44 (0)1327 312262 Email: office@dexcel.com

Patients that are concerned about the change in appearance of their ViePax 150 mg medication may be reassured that no safety or efficacy implications have been identified for this change. Please contact Dexcel medical information should you require further details.

This Direct Healthcare Professional Communication has been disseminated to coincide with the new formulation ViePax XL 150 mg prolonged-release tablets entering the supply chain.

Please report any adverse events associated with ViePax XL 150 mg prolonged-release tablets or the switch to the new round tablet formulation to the MHRA.

Call for reporting

Suspected adverse drug reactions (ADRs) should be reported to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Card website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting, please provide as much information as possible.

Company contact point

If you require additional information please contact Dexcel medical information by telephone (01748 828784) or email (Dexcel@EU.ProPharmaGroup.com).

The ViePax XL 150 mg prolonged-release tablets SmPC, PIL and summary product information describing this formulation change can be found on the eMC website (https://www.medicines.org.uk/emc/).

Yours faithfully,

Andrew Ridsdale
Managing Director, Dexcel Pharma Ltd

Dexcel Pharma Ltd
7 Sopwith Way, Drayton Fields Industrial Estate, Daventry, Northamptonshire, NN11 8PB, United Kingdom
Tel: +44 (0)1327 312266 Fax: +44 (0)1327 312262 Email: office@dexcel.com