Prescribing Tip For Information





Xaqua (metolazone) 5mg tablets: exercise caution when switching patients between metolazone preparations

In light of new information issued by the MHRA this tip is an update to prescribing tip 378 which was originally circulated to practices on 10th November 2022

Xaqua is a new licensed formulation of metolazone. Good prescribing practice recommends the prescribing of a licensed formulation (Xaqua) in preference to unlicensed imported metolazone preparations in new patients.

It has been rated AMBER 0 by Lancashire and South Cumbria Medicines Management Group (LSCMMG)

Before requesting prescribing in primary care patients must be established on a stable dose of metolazone for at least 2 weeks with stable urea and electrolytes (including creatinine) and a stable body weight before discharge.

Ongoing monitoring of urea and electrolytes (including creatinine) should be carried out on a monthly basis and the patients' weight and blood pressure should be monitored at each clinic visit.

Healthcare professionals have expressed concerns to the MHRA with respect to **switching** patients between metolazone preparations due to potential differences in the bioavailability and dosing instructions between Xaqua and unlicensed imported metolazone preparations.

The MHRA sought independent advice from Expert Advisory Groups of the Commission on Human Medicines, which recommended that the Marketing Authorisation Holder for Xaqua circulate a <u>letter to healthcare professionals</u> to reinforce key messages about initiating metolazone treatment or switching to Xaqua.

The <u>product information</u> for Xaqua has been updated to clarify that references to comparative bioavailability with other metolazone products relate specifically to Metenix (a formerly licenced product, which was withdrawn in the UK in March 2012 for commercial reasons) and not to any other metolazone preparations.

Advice on switching to Xaqua

- Specialists should manage the switching of patients already taking an unlicensed imported metolazone product to Xaqua.
- If switching to Xaqua is appropriate, the dose of metolazone provided as Xaqua may need to be adjusted to take account of <u>individual patient factors</u>, and the difference in bioavailability between Xaqua and the metolazone preparation being replaced (where that information is available).
- An option may be to reduce the dose by half (from unlicensed metolazone to Xaqua) and/or adjust the frequency
 of dosing of Xaqua (for example, from unlicensed metolazone daily to Xaqua on alternate days). The dose can
 then be titrated upwards under increased monitoring, if necessary.
- Arrangements for monitoring should be made on an individual basis after an assessment of the individual clinical risk.

Advice on continuing treatment with unlicensed metolazone

If switching is not considered clinically appropriate it should be highlighted to the patient precisely which metolazone preparation they are receiving (including manufacturer, brand name (if available) and dose). The prescription and supply of metolazone should be product-specific and documented clearly, especially for transfers of care.