

Prescribing tip for actioning by practice

Dapagliflozin (Forxiga): no longer authorised for treatment of type 1 diabetes mellitus



The authorisation holder for dapagliflozin has withdrawn the indication for type 1 diabetes mellitus. The removal of the type 1 diabetes indication is not due to any new safety concerns and the other indications of dapagliflozin are unchanged.

On 25 October 2021, the marketing authorisation holder for dapagliflozin withdrew the indication for type 1 diabetes across Europe and in the UK. A [letter was sent to UK healthcare professionals](#) to inform them of the withdrawal. As such, patients with type 1 diabetes should discontinue dapagliflozin 5mg in consultation with their specialist diabetes physician as soon as clinically practical.

Advice for healthcare professionals:

- dapagliflozin 5 mg is no longer authorised for the treatment of patients with type 1 diabetes mellitus
- the removal of the type 1 diabetes indication is not due to any new safety concerns and the other indications of dapagliflozin are unchanged
- dapagliflozin should be reviewed and discontinued in patients with type 1 diabetes by or in consultation with a physician specialised in diabetes care as soon as clinically practical
- after stopping dapagliflozin treatment, frequent blood glucose monitoring is recommended
- an increased insulin dose may be needed, which should be undertaken carefully to minimise the risk of hypoglycaemia or hyperglycaemia
- diabetic ketoacidosis is a known risk with use of dapagliflozin in all patients with diabetes, but it occurs more frequently in patients with type 1 diabetes than those with type 2 diabetes
- additional risk minimisation materials such as the patient alert card and the healthcare professional guide, used to mitigate the risks in patients with type 1 diabetes are no longer available
- report suspected adverse drug reactions associated with use of dapagliflozin on a [Yellow Card](#)

Go to [Dapagliflozin \(Forxiga\): no longer authorised for treatment of type 1 diabetes mellitus - GOV.UK \(www.gov.uk\)](#) for more information.

To contact the Medicines Optimisation Team please phone 01772 214302

If you have any suggestions for future topics to cover in our prescribing tips please contact Nicola.schaffel@nhs.net