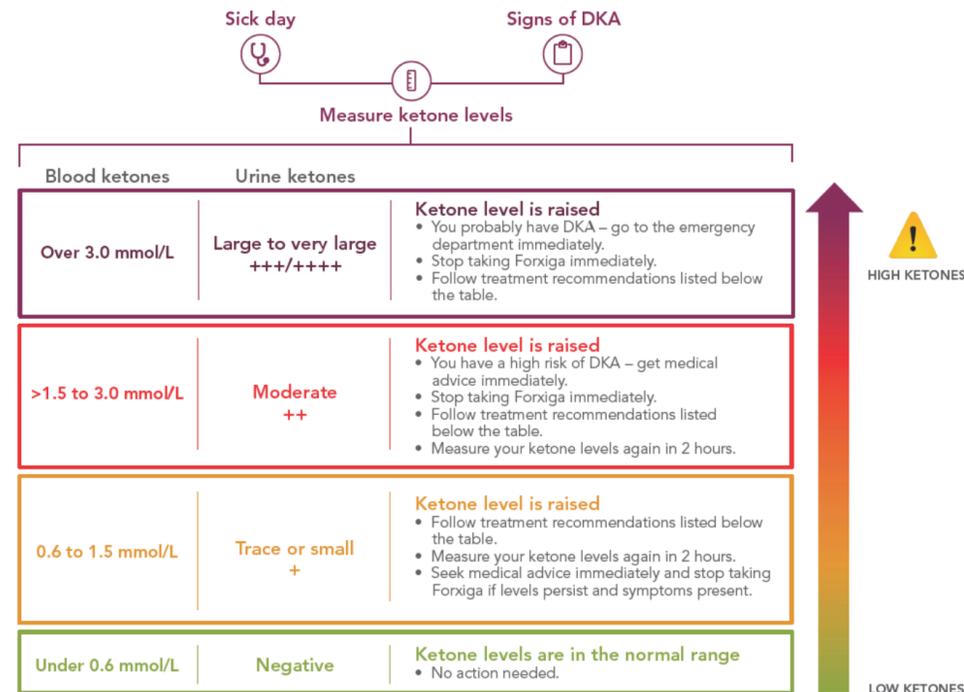


General guidance on ketone monitoring

- In the diagram below, there is some general guidance on how to monitor ketones (urine or blood).
- Specific guidance individual to you will be written on the Worksheet by your Doctor or Nurse, and on your ketone meter – this may be different to this general guidance.
- **Always follow your Doctor or Nurse's specific guidance and the readings on your ketone meter.**



Treatment recommendations for any raised ketones (or clinician's guidance)

- You may need to take extra insulin and drink water.
- Check your blood sugar - you may need to take extra carbs if blood sugar is normal or low.

Doctor's name: _____ Doctor's signature: _____ Date: _____

Patient's name: _____ Patient's signature: _____ Date: _____

This guide is for people with type 1 diabetes and their carers only.

7. What situations might increase my risk of DKA?

The risk of DKA may increase if you temporarily reduce or miss insulin doses.

Therefore, make sure you take extra care and look out for signs of DKA in any situation where your insulin dose has been lowered.

The risk can also increase in certain situations that put stress on the body.

Each of the following may trigger DKA and should be considered when you have your education session with your Doctor or Nurse:

- Illness or infection (i.e. what sick days are for you and how to handle them)
- Fasting (not eating for some reason)
- Sudden decreases in insulin dose (such as missed insulin injections, or issues with your insulin pen or pump)
- Physical exercise
- Drinking alcohol
- Surgery
- Loss of too much fluid from your body (dehydration)

Do not start caloric-restricted, low carbohydrate diet or ketogenic diet during Forxiga treatment.

8. Where do I find further information about Forxiga?



This material, the Patient Alert Card, and the Patient Information Leaflet (PIL) are available online at www.associateddrug.com/frx.pat.mt

9. Where do I report side effects?

If you have any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form available online at <http://www.medicinesauthority.gov.mt/adportal> and sent to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt. Adverse Events should also be reported to Associated Drug Company Limited on: 00356 2277 8115.

When reporting any side effects, make sure you explain that you have type 1 diabetes.



Important Safety Information about Forxiga (dapagliflozin) – for type 1 diabetes only

For people with type 1 diabetes mellitus and their carers to minimise the risk of Diabetic Ketoacidosis (DKA)

Patient and Carer Guide

This guide is for people with type 1 diabetes and their carers only.



5. How do I minimise the risk of getting DKA?

You need to:

- **Follow the general guidance in this section AND**
- **Follow the ketone monitoring guidance (on page 10) and any other advice provided by your Doctor or Nurse in the education session.**

The advice from your Doctor or Nurse may be different than the general guidance below – **always** follow the advice from your Doctor or Nurse, which is individual to you.

General guidance

- **Measure your ketones**

Measure your ketone levels regularly for 1-2 weeks after you start taking Forxiga. If you either have signs of DKA or you are having 'a sick day' or another situation with a higher risk of DKA, measure your ketone levels as directed by your Doctor or Nurse. The ketone monitoring guidance on page 10 will tell you which action to take based on your ketone levels.

- **Measure your blood sugar levels and always take your insulin as prescribed**

Monitor blood sugar levels as directed by your Doctor or Nurse. At times when you need to lower your insulin dose to prevent hypoglycaemia, reduce the dose very carefully to avoid DKA. You also may need to temporarily stop using Forxiga. This may be when you have a short-term illness or are fasting. You may restart using Forxiga when you have recovered or started eating again.

- **Adjust your diet as needed**

Before and during physical activities or when drinking alcohol, you need to:

- take more carbohydrates rather than lowering the insulin dose.
- avoid lowering the insulin dose by more than 20%.

If you are an insulin pump user:

- you have a higher risk of DKA.
- you should only take Forxiga if you are experienced in pump use.
- talk to your Doctor or Nurse about how to prevent insulin decreases when using your pump.
- monitor ketones 3-4 hours after changing pump materials and whenever you think insulin has been interrupted - regardless of glucose level.
- you should take insulin injections within 2 hours of any unexplained high blood glucose or ketone levels and interrupt Forxiga treatment.

6. What should I do if I think I have DKA?

- **Contact a Doctor or go to the hospital straight away.**
- **Tell the Doctor or medical staff that you have type 1 diabetes and you are using Forxiga (dapagliflozin) – and show them your Patient Alert Card and a list of any other medicines you are taking.**
- **Stop taking Forxiga immediately.**

You may need to take extra insulin, drink water, and if your blood sugar is normal or low, you may need to take carbohydrates.

Education Worksheet

Before you start taking Forxiga, you must take part in an education session with your Doctor or Nurse. This is to educate you about DKA and help minimise your risk of DKA.

- Your Doctor or Nurse may complete the Education Worksheet with you. With your Doctor or Nurse, write down any important guidance in the Worksheet below.
- Keep a copy of the Worksheet including any additional written guidance with you at all times.

Write down:

1) What 'sick days' are for you

- How to handle sick days – including what food to eat and how to handle interrupting Forxiga treatment

2) How and when to monitor ketones (this advice may differ from the general ketone monitoring guidance on page 10)

How:

When:

3) Actions you should take in DKA risk situations relevant only to you (circle any that apply and write specific actions below the list)

Risk Situation

- 1) Illness or infection (i.e. sick day rules)
- 2) Fasting
- 3) Sudden decreases in insulin dose (missed dose/issues with pen or pump)
- 4) Physical exercise
- 5) Drinking alcohol
- 6) Surgery
- 7) Loss of too much fluid from your body (dehydration)

Actions for risk situations (if applicable) and other guidance:

Note to Doctor/Nurse: Select specific situations which apply to the patient and note any other important guidance

4) How and when to talk to a Doctor or Nurse or get urgent medical help

How:

When:
