Department of Health & Social Care

NHS

Supply Disruption Alert

SDA/2021/005 Issued: 04 March 2021

Repaglinide 1mg and 2mg tablets

Summary

- Generic repaglinide 1mg and 2mg tablets are out of stock until early May 2021.
- Limited quantities of repaglinide 500 microgram tablets remain available but are unable to support any increase in demand.
- A limited quantity of Prandin (repaglinide) 500 microgram, 1mg and 2mg tablets remain available but are also unable to support any increase in demand.
- Unlicensed supplies of repaglinide 1mg and 2mg tablets have been sourced.
- Prescribers will need to review all affected patients and assess ongoing need for repaglinide. If ongoing treatment is required, consideration should be given to prescribing an alternative glucose lowering medication where unlicensed imports of repaglinide are not appropriate.

Action

All healthcare professionals in primary, secondary or specialist healthcare services who prescribe or supply repaglinide tablets should be aware of the following advice regarding:

All patients

- Clinicians should defer initiating new patients on repaglinide tablets until the supply disruption is resolved.

For patients prescribed repaglinide in Primary Care

- GPs should identify all patients currently prescribed repaglinide and:
    - make early contact with the patient or patient's carer to review ongoing need for repaglinide;
    - if ongoing treatment is required, consider prescribing unlicensed repaglinide tablets (see advice below; prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary);
    - if unlicensed repaglinide tablets are not appropriate, consider prescribing an alternative glucose lowering agent with choice of therapy based on patients' characteristics and comorbidities;
    - encourage patients who routinely monitor blood capillary glucose to continue to do so as recommended in national guidelines;
    - continue to monitor HbA1c as recommended in national guidelines; and
    - make early contact with specialists in secondary care for advice on management options if required.
- When repaglinide is resupplied, GPs should review whether patients are stable on their new treatment regimens and consider:
    - if the patient is stable, continue their new treatment regime; or

- if the patient is unstable, or has issues with adherence on the new regime or has a preference for repaglinide, recommence repaglinide at their previously tolerated dose (if they were stable on that dose prior to switch, and there has been no significant change to lifestyle, e.g. mealtimes, that might warrant re-titration of dose).

For patients prescribed repaglinide in Secondary Care, clinicians should:

- proactively identify all patients under their care (including those referred by primary care) who are currently prescribed repaglinide; and
- ensure patients are reviewed in a timely manner, that individualised management plans are agreed and enacted and communicated to the patient's GP.

Product details

Repaglinide 1mg and 2mg tablets (Viatris and Rivopharm UK Limited)

Problem / background

Viatris are currently out of stock of repaglinide 1mg and 2mg tablets until early May 2021 due to regulatory issues. Rivopharm UK Limited are out of stock due to manufacturing issues and are unable to confirm a resupply date.

Repaglinide, a fast-acting insulin secretagogue, is licensed for the treatment of adults with type 2 diabetes mellitus whose hyperglycaemia can no longer be controlled satisfactorily by diet, weight reduction and exercise. It is also licensed in combination with metformin for the treatment of adults with type 2 diabetes mellitus who are not satisfactorily controlled on metformin alone. Treatment should be initiated as an adjunct to diet and exercise to lower the blood glucose in relation to meals. It has a limited place in patients with irregular mealtimes where glycaemic control has proved difficult with conventional therapy; patients who skip a meal (or add an extra meal) are instructed to skip (or add) a dose for that meal.

There are no alternative drugs in the meglitinide class on the market since nateglinide tablets were discontinued in 2020.

Advice on switching patients to alternate therapies

Sulfonylureas are insulin secretagogues with a similar mechanism of action, though a longer duration of action, to repaglinide. Therefore, they may be a suitable alternative medication for patients in whom repaglinide withdrawal is not considered appropriate.

In line with NICE guidance, adults with type 2 diabetes are not routinely offered self-monitoring of blood glucose levels unless:

- the person is on insulin;
- there is evidence of hypoglycaemic episodes;
- the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery; or
- the person is pregnant or is planning to become pregnant. For more information, see the NICE guideline on diabetes in pregnancy.

If regular blood glucose monitoring is not required according to NICE, the effectiveness of medication switches will be gauged over longer periods using HbA1c values.

Other classes of glucose lowering drug may be considered appropriate with choice based on patients' comorbidities and factors that are usually taken into account when diabetes treatment is escalated e.g. co-existing obesity, cardiovascular disease, impaired renal function, frailty, etc.

See link for national guidance for alternative treatment options to repaglinide, for its licensed indications: Type 2 diabetes management in adults

Unlicensed imports

Unlicensed imports

The following specialist importers have confirmed they can source unlicensed repaglinide tablets (please note, there may be other companies that can also source supplies):

- Alium Medical
- Mawdsley's Unlicensed

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:

- Prescribing unlicensed medicines, General Medical Council (GMC)
- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative, prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
  - Repaglinide 1mg tablets (imported)
  - Repaglinide 2mg tablets (imported)
- Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Distribution

Trusts (NHS boards in Scotland)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E nurses
- All departments
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Cardiothoracic departments
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- Community hospitals
- Community nurses
- Day surgery units
- Diabetologists
- Dieticians
- District nurses
- EBME departments
- Emergency Preparedness and Response officer
- Endocrinologists
- Equipment stores
- Equipment libraries and stores
- Haematologists
- Hospital pharmacies
- Hospital pharmacists
- Intensive care medical staff
- Intensive care nursing staff (adult)
- Intensive care units
- Intensive care, directors of
- Medical directors
- NHS walk-in centres
- Occupation health departments
- Outpatient clinics
- Palliative care teams
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers

- Respiratory specialists
- Risk managers
- Supplies managers
- Walk-in centres

NHS England regional teams
For onward distribution to all relevant staff including:

- Community Pharmacists

General Practice
For onward distribution to all relevant staff including:

- General practitioners
- Nutritional nurse specialists
- General practice managers
- General practice nurses
- Non-medical prescribers in General Practice

Independent distribution
Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Enquiries

Send enquiries about this notice to the DHSC Medicines Supply Team, quoting reference number **SDA/2021/005 -** Email: DHSCmedicinesupplyteam@dhsc.gov.uk