

Greater East Midlands Commissioning Support Unit in association with
Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

Lincolnshire Prescribing and Clinical Effectiveness Bulletin

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PRESCRIBING OF GLUTEN FREE FOODS (SECOND EDITION)

Key Recommendations

- Only patients with established gluten enteropathy (including coeliac disease, steatorrhoea due to gluten sensitivity and dermatitis herpetiformis) with or without coexisting wheat sensitivity should receive gluten free (GF) foods on prescription. Gluten enteropathy should be confirmed by biopsy wherever possible.
- The GF diet is potentially very restrictive and all patients should be referred to a dietitian for dietary assessment and advice as soon as possible after diagnosis. A prescribing pathway is provided as Appendix 1. It is very important to ensure that the patient understands the diet and the complications which can occur due to poor compliance with it. As part of the dietary assessment, the patient will be provided with information on appropriate quantities to order based on Coeliac UK age and sex specific quantities guidance (see Appendix 2).
- PACEF are in support of the prescription of staple GF products for patients with an ACBS approved indication. Staple foods are defined as: bread, bread mixes, pasta, flour, pizza bases, breakfast cereals, crackers and crispbreads. Quantities prescribed should be tightly controlled within quantities defined in the Coeliac UK prescribing guide (see Appendix 2).
- In January 2011, Coeliac UK issued a statement confirming that they could not support the prescribing of non-staples such as sweet biscuits, cookies, cake mixes and cakes as the regular consumption of these foods is not consistent with healthy eating messages. As a result of this, non-staple GF foods should only be prescribed in exceptional circumstances.
- Nearly 6% of the expenditure on GF foods in Lincolnshire is for non-staple GF products; this equates to nearly 13% of prescription volume. Patient review should ensure that prescribing of non-staple GF foods is kept to a minimum and only sanctioned in exceptional circumstances.
- Patients are free to supplement their prescribed GF diet with commercially produced non-staple GF products which are available to buy from supermarkets, health food stores and some pharmacies.
- Patients should only receive GF products on prescription up to the recommended monthly quantity as designated in the Coeliac UK prescribing guide (see Appendix 2). The quantities recommended in the prescribing guide are higher than needed for some patients. In exceptional circumstances and subject to dietitian review, larger quantities can be agreed on prescription for patients with particular difficulties.
- Prescribers are urged to review all prescriptions for GF foods to ensure that patients cannot continue to order in quantities in excess of the Coeliac UK prescribing guide unless exceptional individual circumstances have been identified and agreed.
- Over-ordering of fresh GF bread can be extremely wasteful of NHS resources, particularly if surplus quantities go out of date and are wasted.

Where fresh GF bread is prescribed, patients should be advised to freeze surplus quantities immediately upon receipt as fresh GF bread deteriorates rapidly if stored at room temperature. GF bread making at home can be a more cost-effective and palatable way of ensuring that GF bread is available in the home.

- **A small percentage of GF prescribing (less than 1%) is for products that are not approved for NHS prescribing at all.**
- **Coeliac disease does not exempt individuals from prescription charges, although a pre-payment certificate (PPC) can reduce the cost of prescriptions. If an individual receives more than 4 prescription items in three months or 14 items in twelve months, a PPC can work out cheaper than single charges for each item.**
- **All prescribers are advised to refer to the Coeliac UK prescribing guideline *Gluten-free foods: a revised prescribing guide 2011* for further information www.coeliac.org.uk/revisedprescribingguideline2011**

Introduction

Coeliac disease (CD) is a life-long autoimmune disease in which gluten damages the villi in the small intestine, and which improves morphologically when gluten is removed from the diet. Patients suffering from coeliac disease and dermatitis herpetiformis (DH) (another disease related to gluten intolerance) need to adhere to a lifelong gluten free (GF) diet. Many foods are naturally free of gluten and present no problems to these patients. In order to maintain a GF diet, patients need to exclude all foods containing wheat, rye and barley; manufactured GF products often contain wheat from which gluten has been removed. The vast majority of coeliac patients can include oats in their diet as long as they are uncontaminated by any other gluten containing cereal. A number of GF oat products are available; they provide an important source of variety in what can be a very restricted diet. The British Society of Gastroenterology recommends that oats are excluded for the first 6-12 months of a GF diet and uncontaminated oats reintroduced if the patient wishes.

In untreated CD, damage to the surface of the small intestine results in a reduced ability to digest and absorb food; this can cause malabsorption of essential nutrients such as iron, folic acid and calcium. In infants and children this can result in faltering growth, unexplained anaemia, chronic diarrhoea and abdominal distension. In adults, presenting symptoms include general ill health, tiredness, reduced appetite, weight loss, mouth ulcers, abdominal bloating, diarrhoea, constipation and anaemia. Health risks linked to untreated CD include poor growth in childhood, osteopenia, osteoporosis, infertility, increased risk of non-Hodgkins lymphoma, Hodgkins lymphoma, intestinal malignancy and iron, vitamin B12 or folate deficiency. These risks are thought to be reduced by a strict GF diet.

Dermatitis Herpetiformis (DH) is an itchy blistering skin eruption which is due to gluten sensitivity. The sensitivity also affects the small intestine in the majority of patients giving rise to a mild form of CD. The GF diet cures the skin rash and treats the CD and should therefore be continued for life.

Gluten Free Prescribing in Lincolnshire: Some Facts and Figures

- In the last year, nearly £500,000 was spent on the prescribing of GF foods across the four Lincolnshire CCGs.
- An extensive range of products were prescribed including: bread, pasta, pizza bases, breakfast cereals, crackers, cake mixes, bread mixes, biscuits, cakes, pastry mixes and gravy mixes.
- Almost 6% of the cost of prescribed GF foods was for non-staple items, such as biscuits, cookies, cakes and cake mixes; this accounts for 13% of the volume.
- Nearly 1% of the expenditure on GF foods was for non-Tariff approved products.

September 2013 Quarter	Gluten Free Prescribing		
	Actual Cost	No of Prescribed Items	Percentage Items Prescribed as Non-Staples
Lincolnshire East CCG	£43,601	3,220	14.10%
Lincolnshire West CCG	£40,272	3,069	14.34%
South Lincolnshire CCG	£22,901	1,748	12.19%
South West Lincolnshire CCG	£17,552	1,275	8.78%
Lincolnshire	£124,326	9,312	13.09%

PACEF Recommendation:

Between 9 and 14% of the volume of GF prescribing is for non-staple GF products such as sweet biscuits, cookies, cakes and cake mixes. Prescribers are urged to review all patients prescribed non-staple GF products with a view to discontinuing supply unless the patient's circumstances are exceptional.

Gluten Free Foods on Prescription

Prescribable GF foods are defined as borderline substances in the *Drug Tariff* (Part XV) and can *only* be prescribed for patients with established gluten enteropathy with or without co-existing wheat sensitivity.

PACEF Recommendation:

Only patients with established gluten enteropathy (including coeliac disease, steatorrhoea due to gluten sensitivity and dermatitis herpetiformis) with or without co-existing wheat sensitivity should receive GF foods on prescription. Gluten enteropathy should be confirmed by biopsy wherever possible.

Staple GF Foods

Among the types of food that are prescribable are staples such as bread (various types, fresh and long-life, baked and part-baked), bread mixes, pasta (various types), flour (various types), pizza bases, breakfast cereals, crackers and crispbreads. As these products are classified as borderline substances each FP10 prescription form should be endorsed 'ACBS'. Care should be taken to ensure that the patient's diagnosis matches one of the approved indications for the product as listed in Appendix 2 of the *BNF* or Part XV of the *Drug Tariff*.

PACEF Recommendation: PACEF are in support of staple GF products continuing to be prescribed for patients with an ACBS approved indication. These include: bread, rolls, bread mixes, pasta, flour (various types), pizza bases, breakfast cereals, crackers and crispbreads. Quantities prescribed should be tightly controlled within Coeliac UK age and sex specific quantities guidance as detailed in Appendix 2.

Non-staple GF foods

Some GF foods defined as non-staples are still available on prescription. These include sweet biscuits, cookies, cake mixes, cakes and iced buns. In January 2011, Coeliac UK issued a statement confirming that they could not support the prescribing of non-staples such as sweet biscuits and cake mixes as the regular consumption of these foods is not consistent with healthy eating recommendations. However, it is recognized that compliance with a GF diet can be challenging, particularly for children and adolescents and the consequences of poor compliance with the GF diet can have serious health consequences for the individual. As a result of this, non-staple GF foods should only be prescribed in exceptional circumstances.

PACEF Recommendation: Non-staple GF foods such as sweet biscuits, cookies, cake mixes, cakes and iced buns should only be prescribed in exceptional circumstances. Patients are free to supplement their prescribed GF diet with commercially produced non-staple GF products which are available to buy from supermarkets, health food stores and some pharmacies. Prescribers are urged to review all prescriptions for non-staple foods with the intention to terminate supply unless exceptional circumstances are identified.

Quantities to be prescribed

Coeliac UK (a charity supported by the Primary Care Society for Gastro-enterology and the British Dietetic Association) has produced guidelines outlining the quantities of GF foods likely to be required by coeliac patients. Recommendations are made based on the patient's age and activity levels allowing a specific number of "units" on prescription each month (see Appendix 2). These quantities may be more than is needed by some patients.

PACEF Recommendation:

Patients should only receive GF products on prescription up to the recommended monthly quantity as designated in the Coeliac UK prescribing guide (see Appendix 2). The quantities recommended in the prescribing guide are higher than needed for some patients. It is expected that the majority of patients will supplement their prescribed food items, particularly of non-staple items, with additional GF foods from supermarkets, health food stores or pharmacies. In exceptional circumstances and subject to dietitian review, larger quantities can be agreed on prescription for patients with particular difficulties. Prescribers are urged to review all prescriptions for GF foods to ensure that patients cannot continue to order in quantities in excess of the Coeliac UK prescribing guide recommendations unless exceptional circumstances have been identified and agreed.

Gluten free, wheat-free products

Gluten free products are not necessarily wheat free. Some patients with CD may require a fully wheat free diet if their symptoms do not subside on the gluten-free diet. As part of the review, it is important to check if the patient has any additional food allergies or intolerances. Gluten free, wheat free products are available on prescription.

Gluten free bread and bread rolls

Fresh GF bread on prescription creates all kinds of problems for the NHS. These products are baked to order and are often only available on direct order from their manufacturer. The cost of these products can be variable from different suppliers and wholesalers; associated delivery charges can be high (although not from all manufacturers). Many products are only available in multiples of six to eight loaves or packs of rolls (depending upon the manufacturer). Fresh bread is delivered to pharmacies/dispensing practices once or twice a week. It will keep for up to 8 days and if frozen on delivery will keep for up to 4 weeks. Failure to freeze surplus supplies on delivery can result in significant waste. Single fresh GF loaves are available from supermarkets.

PACEF Recommendation: Over-ordering of fresh GF bread can be extremely wasteful of NHS resources, particularly if surplus quantities go out of date and are wasted. Where fresh GF bread is prescribed, patients should be advised to freeze surplus quantities immediately upon receipt as fresh GF bread deteriorates rapidly if stored at room temperature.

Gluten free flours and flour mixes

Flour is considered a staple food and as such is suitable for prescribing. Bread mixes are more expensive, although they can be cost-effective if used as a substitute for fresh bread.

PACEF Recommendation

GF bread making at home can be a more cost-effective and palatable way of ensuring that GF bread is available in the home.

Prescription Charges and Pre-Payment Certificates

Coeliac disease does not exempt individuals from prescription charges, although a pre-payment certificate (PPC) can reduce the cost of prescriptions. If an individual receives more than 4 prescription items in three months or 14 items in twelve months, a PPC can work out cheaper than single charges for each item.

The Coeliac UK Food and Drink Directory

The *Food and Drink Directory* produced by Coeliac UK is an invaluable reference source available to the patient that enables the GF status of a wide range of products to be easily checked. Regular updates are available online. Patients are encouraged to join Coeliac UK in order to receive the Directory and regular updates.

Gluten Free Medicines

Many medicines contain flour or starch as a filler. If a medicine contains wheat starch, this will be indicated on the label and the accompanying patient information leaflet (PIL). Wheat starch of pharmaceutical quality is highly processed and considered gluten-free; any licensed medicines that contain wheat starch are suitable for people with CD. Standard advice from the Medicines and Healthcare products Regulatory Agency (MHRA) is that all licensed pharmaceutical preparations (including licensed over-the-counter medicines) can be considered to be gluten-free. However, the GF status of unlicensed medicines, dietary supplements and other health-related products will need to be checked. Queries relating to the contents of licensed medicines can usually be answered with reference to the Summary of Product Characteristics (SPC) or Patient Information Leaflet (PIL) relating to the product. Patients should be directed to their local community pharmacist for advice. Healthcare professionals will need to seek advice from their local medicines information centre where information is not readily available. Trent Medicines Information Service is contactable by email and telephone:

[email: medicines.info@uhl-tr.nhs.uk](mailto:medicines.info@uhl-tr.nhs.uk)

Tel: 0116 258 6491

The Prescription Process (see Algorithm)

The GF diet is potentially very restrictive and all patients should be referred to a dietitian as soon as possible after diagnosis. It is very important to ensure that the patient understands the diet and the complications which can occur due to poor compliance with it.

PACEF Recommendation:

Following initial diagnosis, the patient should be referred to a dietitian for dietary assessment and advice.

United Lincolnshire Hospitals Dietetic Service

On receipt of a dietetic referral, an appointment will be sent out urgently to the patient. At the initial appointment the patient's diet will be assessed and the GF diet will be explained, including ways of ensuring that the diet fits in with the patient's way of life. Relevant literature including a GF diet sheet, GF manufactured products booklet, GF prescribable products list and leaflets for free samples produced by the commercial companies will be provided. The referring doctor will also receive a letter giving details of the major areas discussed in the consultation. Other nutritional requirements of the patient (e.g. calcium requirements) will also be considered. Follow up appointments are offered based on individual patient requirements. Most patients will be offered an annual follow up appointment.

Further Information

Coeliac UK is the national support group for people with CD and DH and is open to those who have been medically diagnosed with either condition. All members receive the *Food and Drink Directory* annually and copies of the magazine *Crossed Grain*. They also provide recipe books and other publications. Local support groups are established across the UK. Dietitians will usually recommend that all patients diagnosed with CD or DH should join Coeliac UK. For further information contact:

Coeliac UK
High Wycombe Office
3rd Floor
Apollo Centre
High Wycombe
Bucks
HP11 2QW

All prescribers are advised to refer to the Coeliac UK prescribing guideline *Gluten-free foods: a revised prescribing guide 2011*
www.coeliac.org.uk/revisedprescribingguideline2011.

Detailed guidelines about diagnosis of CD were published by NICE in NICE Clinical Guideline 86: *Coeliac disease – Recognition and assessment of coeliac disease* (May 2009) (see *PACE Bulletin*, Vol 3, No 11 (October 2009)).

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- Sharon Hayler, Prescribing Adviser, Greater East Midlands Commissioning Support Unit
- Members of the Lincoln branch of Coeliac UK.

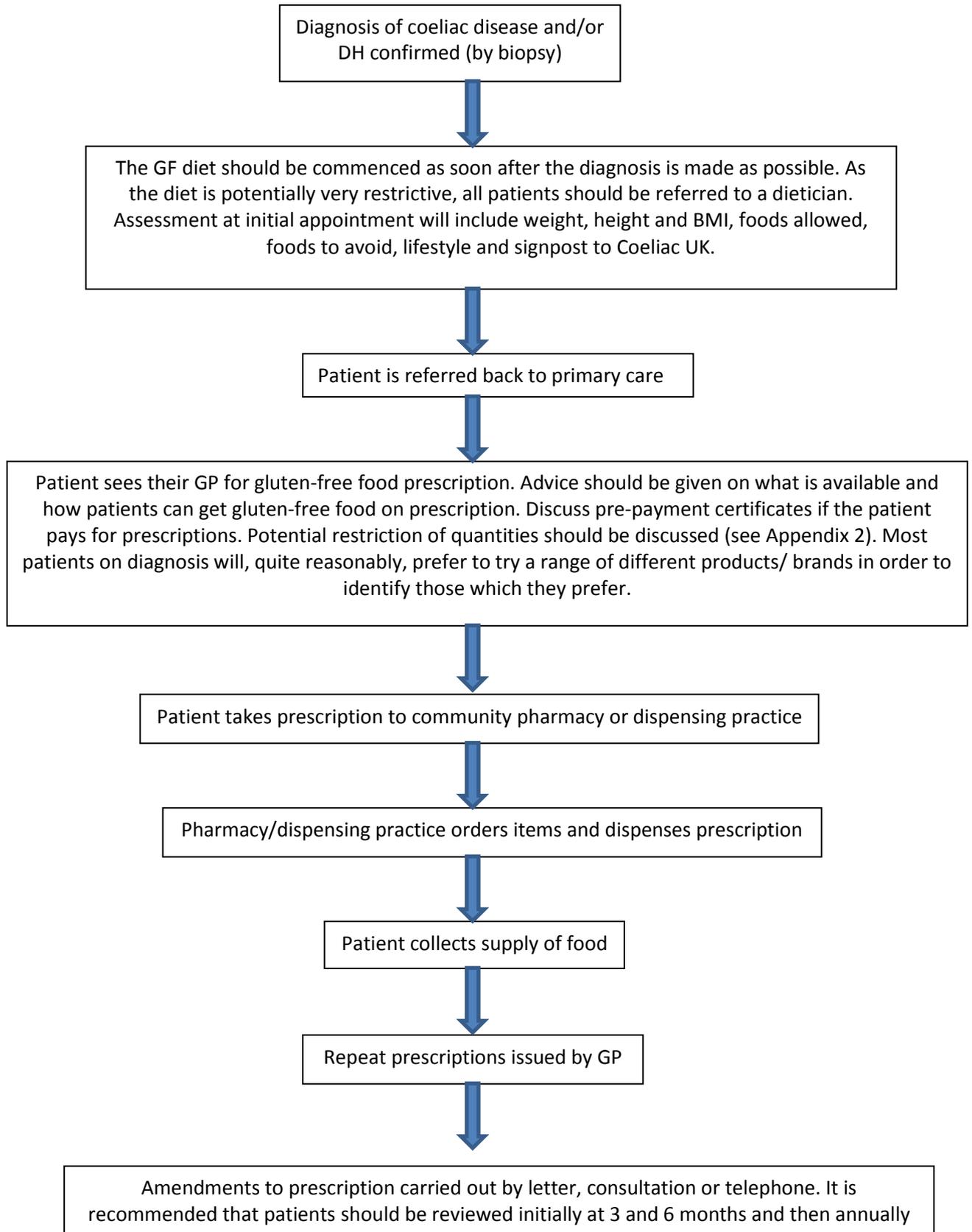
Much of the text has been adapted from local guidance and the Coeliac UK prescribing guideline *Gluten-free foods: a revised prescribing guide 2011* (November 2011).

Stephen Gibson
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Appendix 1

Prescribing of Gluten Free Foods Pathway



Appendix 2: Quantities to be prescribed

Number of units represented by prescribable GF food items

Prescribable food item	No of units
400g bread	1
100 to 250g rolls/baguettes	0.5
250 to 400g rolls/baguettes	1
500g bread mix/flour mix	2
100g crackers/crispbreads	0.5
150g crackers/crispbreads	0.75
200g crackers/crispbreads	1
250g pasta	1
500g pasta	2
2x110g to 2x180g pizza bases	1
500g oats	1.5
300g breakfast cereal	1.5
100 to 170g xanthan gum	1

Approximate monthly requirement (units) for various patient groups

Age group	Recommended number of units	Example of monthly prescription
1–3years	10	6x400g bread (or 3 x 500g mix suitable for making bread) 2x300g breakfast cereal 1 x 250g pasta
4-6years	11	6x400gbread (or 3 x 500g mix suitable for making bread) 2 x 500g pasta 1(2x 110g)or 1(2x 180g) pizza bases
7–10years	13	8x400gbread (or 4 x 500g mix suitable for making bread) 2 x 500g pasta 1(2x 110g)or 1(2x 180g) pizza bases
11–14years	15	8x400gbread (or 4 x 500g mix suitable for making bread) 1 x 500g pasta 2x500g GF oats 2(2x 110g)or 1(2x 180g) pizza bases

15–18years	18	8x400gbread (or 4 x 500g mix suitable for making bread) 3 x 500g pasta 2x300g breakfast cereal 1xcrackers/crispbread
Male: 19–59years	18	8x400g bread (or 4 x 500g mix suitable for making bread) 3 x 500g pasta 2x300g breakfast cereal 1(2x 110g)or 1(2x 180g) pizza bases
Male: 60–74 years	16	8 x 400g bread (or 4 x 500g mix suitable for making bread) 2 x 500g pasta 1 x crackers/crispbreads 2x500g GF oats
Male: 75 + years	14	8 x 400g bread (or 4 x 500g mix suitable for making bread) 1 x 500g pasta 1 x crackers/crispbreads 2x500g GF oats
Female: 19–74 years	14	8x400g bread (or 4 x 500g mix suitable for making bread) 1 x 500g pasta 1 x crackers/crispbreads 2x300g breakfast cereal
Female: 75 + years	12	6 x 400g bread (or 4 x 500g mix suitable for making bread) 1 x 500g pasta 1 x crackers/crispbreads 2x500g GF oats
Breast Feeding	Add 4 units	1 x 400g bread 1 x 500g pasta 1 x crackers/crispbreads
3 rd trimester pregnancy	Add 1 unit	1 x crackers/crispbreads

Additional units may be required; this should be assessed on an individual basis by a dietitian.