PARACETAMOL 500MG CAPSULES
PL 20395/0081

UKPAR

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Lay Summary

On 11 August 2011, the MHRA granted Relonchem Limited a Marketing Authorisation (licence) for Paracetamol 500mg Capsules.

Paracetamol 500mg Capsules contain paracetamol as the active ingredient. Paracetamol is an analgesic (pain killer) and an antipyretic (helps reduce body temperature when you have a fever).

Paracetamol 500mg Capsules are used for the relief of mild to moderate pain including:
- Rheumatic and muscular pain
- Backache, toothache
- Neuralgia (severe nerve pain), period pain
- Migraine, headache
- Fevers, colds and flu.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Paracetamol 500mg Capsules outweigh the risks; hence a Marketing Authorisation has been granted.
PARACETAMOL 500MG CAPSULES
PL 20395/0081

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Paracetamol 500mg Capsules (PL 20395/0081) to Relonchem Limited on 11 August 2011. This medicine has a General Sales Licence (GSL) and is indicated for the treatment of mild to moderate pain, including:

- rheumatic and muscular pain
- backache
- neuralgia
- migraine and headache
- toothache
- period pains
- the symptomatic relief of feverishness, colds and flu.

This application for Paracetamol 500mg Capsules is submitted according to Article 10c of Directive 2001/83/EC, cross-referring to Paracetamol/Doans 500mg Capsules, which were originally approved and licensed to Eastern Pharmaceuticals Limited on 17 May 2000 (PL 11382/0061). This licence then underwent a change of ownership to LPC Medical (UK) Limited on 28 January 2005 (PL 19348/0093).

It is considered that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance together with the necessary means for notification of any adverse reaction suspected of occurring.

A Risk Management Plan (RMP) was not submitted and one is not required for an application of this type.

No new data were submitted nor were they necessary for this “simple” application, as the data are identical to that of the previously granted cross-reference product.
1. INTRODUCTION
This is a “simple” application for Paracetamol 500mg Capsules (PL 20395/0081) submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is Relonchem Limited, 27 Old Gloucester Street, London, WC1 3XX, United Kingdom.

This application cross-refers to Paracetamol/Doans 500mg Capsules, which were originally approved and licensed to Eastern Pharmaceuticals Limited on 17 May 2000 (PL 11382/0061). This licence then underwent a change of ownership to LPC Medical (UK) Limited on 28 January 2005 (PL 19348/0093).

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Paracetamol 500mg Capsules. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains 500mg paracetamol. The finished product is packaged in two types of blisters composed of:

i) White opaque rigid polyvinyl chloride (PVC) film unplasticised 250µm, with hard tempered aluminium foil.

ii) Glassine paper 35g/sqm, adhesive lacquer 2.5g/sqm, aluminium foil (9 micron), heatseal coating 7.0g/sgm and PVC 250 micron.

The blisters are packaged in cartons. The product comes in pack sizes of 8, 12 and 16 capsules.

The proposed shelf-life is 36 months with storage conditions ‘Do not store above 25°C. Store in the original blister in order to protect from moisture’ and Store in original package- for blister pack’. This is consistent with the details registered for the cross-reference product.

2.3 Legal status
General Sales Licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company
Relonchem Limited, 27 Old Gloucester Street, London, WC1 3XX, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.
2.5 Manufacturers
The manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The finished product specification is in-line with the details registered for the cross-reference product. There are extra tests which are not present in the finished product specification for the reference product, but this is not an issue as these tests enhance the quality of the product.

2.9 Drug substance specification
The drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
None of the excipients used contain material of human origin. The supplier of magnesium stearate has confirmed that it is of vegetable origin. A European Pharmacopoeia Certificate of Suitability for TSE has been provided for Gelatin, which is of animal origin. This is confirmed by a statement from the Quality Expert. This information is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included expert statements in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product. A bridging statement has been submitted. This is satisfactory.

The results of consultations with target patient groups ("user testing") are in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that they contain.
Labelling
The artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has included the name of the product in Braille on the packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

A satisfactory non-clinical expert statement has been provided and accepted in-line with the reference product.

A satisfactory justification for the absence of an Environmental Risk Assessment has been provided.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.

A satisfactory clinical expert statement has been provided and accepted in-line with the reference product.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with those previously approved for the cross-reference product and, as such, has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
This application is identical to the previously granted application, Paracetamol/Doans 500mg Capsules, which were originally approved and licensed to Eastern Pharmaceuticals Limited on 17 May 2000 (PL 11382/0061). This licence then underwent a change of ownership to LPC Medical (UK) Limited on 28 January 2005 (PL 19348/0093).

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with paracetamol is considered to have demonstrated the therapeutic value of the compound. The risk:benefit is, therefore, considered to be positive.
### STEPS TAKEN FOR ASSESSMENT

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<th>Description</th>
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<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation Application on 21 September 2010.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 11 October 2010.</td>
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<td>3</td>
<td>Following assessment of the application further information was requested regarding the quality section of the dossier on 24 January 2011 and 18 April 2011.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 14 March 2011 and 07 June 2011 for the quality section.</td>
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<td>5</td>
<td>The application was determined on 11 August 2011.</td>
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PARACETAMOL 500MG CAPSULES
PL 20395/0081

STEPS TAKEN AFTER ASSESSMENT

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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Paracetamol 500mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient: Paracetamol 500mg.
‘For full list of excipients, see section 6.1’

3 PHARMACEUTICAL FORM
Capsule For oral administration.

4 CLINICAL PARTICULARS
4.1 THERAPEUTIC INDICATIONS
For the treatment of mild to moderate pain, including rheumatic and muscular pain, backache, neuralgia, migraine, headache, toothache and period pains and for the symptomatic relief of feverishness, colds and flu.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
The capsules are taken by mouth. Adults: one or two capsules.
The dose should not be repeated more than four times in 24 hours. The dosage should not be continued for more than 3 days without consulting a doctor.

4.3 CONTRAINDICATIONS
Hypersensitivity to paracetamol and/or other constituents. Patients with impaired liver or kidney function and alcoholics could be at risk in taking paracetamol. The hazard of overdose is greater in those with non-cirrhotic liver disease.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
The patient would be informed of:
(i) Do not exceed the recommended dose.
(ii) The desirability/necessity of consulting a doctor if symptoms persist.
(iii) The need to ask the doctor or pharmacist about taking the capsules if they are already on a course of medication.
(iv) The fact that the product contains paracetamol should be stressed and a warning against taking other paracetamol containing products at the same time should be given.
(v) Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with alcoholic liver disease.
(vi) If symptoms persist, consult your doctor.
(vii) Keep out of the reach of children.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 FERTILITY, PREGNANCY AND LACTATION
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol being used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast-feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
None.
4.8 UNDESIRABLE EFFECTS
Allergic reactions and sensitivity are rare but may include skin rashes, drug fever and mucosal lesions.

There have been reports of blood dyscrasias, including thrombocytopenia and agranulocytosis and/or acute pancreatitis, but these were not necessarily causality related to paracetamol. At the recommended dosages, drowsiness, impairment of mental function and methaemoglobinemia have been seen.

4.9 OVERDOSE
Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage.

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:
If the patient
a. Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.
Or
b. Regularly consumes ethanol in excess of recommended amounts.
Or
c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES
5.1 PHARMACODYNAMIC PROPERTIES
Paracetamol has analgesic and antipyretic actions but has no anti-inflammatory properties.

5.2 PHARMACOKINETIC PROPERTIES
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half life varies from about 1-4 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increased concentration.
A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause liver damage.

5.3 PRECLINICAL SAFETY DATA
There is no pre-clinical data of relevance to a prescriber which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS
6.1 LIST OF EXCIPIENTS
Starch 1500, Magnesium Stearate, Sodium Lauryl Sulphate. The capsule shell is opaque red/white gelatin 100 mg, containing as colours Erythrosine (E127), Patent Blue V (E131), Titanium Dioxide (E171), and Quinoline Yellow (E104).

6.2 INCOMPATIBILITIES
None known

6.3 SHELF LIFE
36 months

6.4 SPECIAL PRECAUTIONS FOR STORAGE
Store in original blister in order to protect from moisture. Do not store above 25°C. Store in original package - for blister pack.

6.5 NATURE AND CONTENTS OF CONTAINER
Strips of 8, 12, 16, blisters in a carton. The blisters are white opaque rigid PVC film unplasticised 250 µm, with hard tempered aluminium foil.

Glassine paper 35g/sqm/ Adhesive lacquer 2.5g/sqm/ Aluminium foil (9 micron)/Heatseal coating 7.0g/sgm/ PVC 250 micron with 8, 12, 16 capsules.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
No special precautions required.

7 MARKETING AUTHORISATION HOLDER
Relonchem Limited
27 Old Gloucester Street
London
WC1 3XX
Tel: +44 207 419 5043
Fax: +44 207 419 5024
Email: info@relonchem.com

8 MARKETING AUTHORISATION NUMBER(S)
PL 20395/0081

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
11/08/2011

10 DATE OF REVISION OF THE TEXT
11/08/2011
PATIENT INFORMATION LEAFLET

PARACETAMOL 500mg CAPSULES

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Paracetamol 500mg Capsules carefully to get the best results from them.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Paracetamol 500mg Capsules are and what they are used for
2. Before you take Paracetamol 500mg Capsules
3. How to take Paracetamol 500mg Capsules
4. Possible side effects
5. How to store Paracetamol 500mg Capsules
6. Further information

1. WHAT PARACETAMOL 500mg CAPSULES ARE AND WHAT THEY ARE USED FOR

Paracetamol 500mg Capsules contain the active ingredient paracetamol and are used for the relief of mild to moderate pain, including:
- rheumatic and muscular pain
- backache, toothache
- neuralgia (severe nerve pain), period pain
- migraine, headache
- fevers, colds and flu.

Take special care with Paracetamol 500mg Capsules
Consult your doctor before taking these capsules if you:
- have kidney or liver problems.
- are an alcoholic.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:
- other products containing paracetamol (see 'DO NOT take Paracetamol 500mg Capsules')
- warfarin and other drugs which thin the blood
- cholestyramine (reduces blood cholesterol levels)
- metoclopramide and domperidone (used to treat nausea, vomiting or other stomach problems).

Taking Paracetamol 500mg Capsules with food and drink
Avoid alcoholic drinks whilst taking these capsules.

Pregnancy and Breast Feeding
Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant, planning to become pregnant or breast-feeding.

Driving and using machines
Paracetamol 500mg Capsules are not expected to affect your ability to drive or operate machinery.

2. BEFORE YOU TAKE PARACETAMOL 500mg CAPSULES

DO NOT take Paracetamol 500mg Capsules if you are:
- allergic (hypersensitive) to paracetamol, other pain relievers or any of the other ingredients in the product (see Section 6 on 'What Paracetamol 500mg Capsules contain')
- taking any other paracetamol-containing medicines, i.e. over-the-counter cold remedies.

This medicine is NOT recommended for children under 12 years of age.
3. HOW TO TAKE PARACETAMOL 500mg CAPSULES

Always take Paracetamol 500mg Capsules exactly as your doctor has told you. Swallow each capsule with a drink of water.

**Adults:**
Take one or two capsules every 4 to 6 hours, up to a maximum of 8 capsules in any 24 hour period. You should not take Paracetamol 500mg Capsules for longer than 3 days.

This medicine is **not recommended for children under 12 years of age.**

**WARNING:** DO NOT EXCEED THE STATED DOSE
Contains paracetamol. Do not take with other paracetamol containing products.

If symptoms persist consult your doctor. Do not use for more than 3 days without consulting your doctor.

If you take more Paracetamol 500mg Capsules than you should
It is extremely important to follow the dosage instructions that have been given to you. Do not change your dose without discussing it with your doctor first. Symptoms of overdose include pallor (paleness of skin), nausea, vomiting, anorexia and stomach pain. If you accidentally take more than the recommended dose, or know someone who has, contact your doctor or nearest hospital casualty immediately. Take any remaining medicine and this leaflet with you if possible.

**IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSE, EVEN IF YOU FEEL WELL, BECAUSE OF THE RISK OF DELAYED, SERIOUS LIVER DAMAGE.**

If you forget to take Paracetamol 500mg Capsules
If you miss a dose, take it as soon as you remember. NEVER take a double dose to make up for the dose you have forgotten.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paracetamol 500mg Capsules can cause side effects, although not everybody gets them.
You may suffer an allergic reaction, symptoms of which include skin rashes and itching. If this happens to you, stop taking the capsules immediately and seek urgent medical help.
The following have also been reported:
- hives
- blood abnormalities, but these were not necessarily due to paracetamol treatment
- drowsiness and impaired mental function
- severe liver poisoning in alcoholics.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE PARACETAMOL 500mg CAPSULES

Keep out of the reach and sight of children.
Do not store above 25°C. Store in the original package.
Do not use Paracetamol 500mg Capsules after the expiry date shown on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paracetamol 500mg Capsules contain
The **active** substance is Paracetamol 500mg.
The **other** ingredients are starch 1500, magnesium stearate, sodium lauryl sulphate. The capsule shell is opaque red/white gelatin 100mg, containing as colours erythrosine (E127), patent blue V (E131), titanium dioxide (E171) and quinoline yellow (E104).

What Paracetamol 500mg Capsules look like and contents of the pack
Paracetamol 500mg Capsules are clean, oblong shaped red and white capsules. They are supplied in:
- cartons containing blister strips of 8, 12, 16 capsules.

Marketing Authorisation Holder
Relonchem Limited, 27, Old Gloucester street, London, WC1 3XX
Tel: 0207 419 5043 Fax: 0207 419 5024
Email: Info@relonchem.com
PL:20395/0081

Leaflet was prepared on March 2011
LABELLING

The labelling below is the label mock-ups for the 8 and 16 capsule pack sizes. The marketing authorisation holder has stated that it is not intending to market the 12 capsule pack size at this time; therefore no labelling mock-up has been submitted. The marketing authorisation holder has committed to submit the UK labelling for the 12 capsule pack size for review to the regulatory authority before marketing the 12 capsule pack size.
Each capsule contains 500mg Paracetamol. Also contains Erythrosine (E127), Patent Blue V (E131), Titanium Dioxide (E171) and Quinoline Yellow (E104).

Read the package leaflet before use.

Uses: for the treatment of mild to moderate pain including headache, migraine, neuralgia, toothache, sore throat, period pains, aches and pains. Also for the symptomatic relief of feverishness and colds and flu.

Dosages: Adults, the elderly and children over 12 years of age: Take one or two capsules every 4 to 6 hours up to a maximum of 8 capsules in any 24 hour period.

Do not give to children under 12 years of age except on medical advice.

DO NOT EXCEED THE STATED DOSE

If symptoms persist consult your doctor. Do not continue to use for more than 3 days without consulting a doctor or pharmacist.

DO NOT USE if you suffer from any liver or kidney complaint, or are allergic to any of the other ingredients. If you are pregnant or taking any medication, consult your doctor before taking this medicine.

Contains Paracetamol.

Do not take with any other Paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not store above 35ºC.

Store in the original package.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

For the relief of mild to moderate pain

For oral use.

Marketing Authorisation Holder:
Relonchem Limited,
27 Old Gloucester Street,
London WC1 3XX, United Kingdom.