Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Pregabalin Brown & Burk 25 mg hard capsules
Pregabalin Brown & Burk 50 mg hard capsules
Pregabalin Brown & Burk 75 mg hard capsules
Pregabalin Brown & Burk 100 mg hard capsules
Pregabalin Brown & Burk 150 mg hard capsules
Pregabalin Brown & Burk 200 mg hard capsules
Pregabalin Brown & Burk 225 mg hard capsules
Pregabalin Brown & Burk 300 mg hard capsules

Pregabalin

PL 25298/0292 - 0299

Brown & Burk UK Limited

LAY SUMMARY

Pregabalin Brown & Burk 25 mg hard capsules
Pregabalin Brown & Burk 50 mg hard capsules
Pregabalin Brown & Burk 75 mg hard capsules
Pregabalin Brown & Burk 100 mg hard capsules
Pregabalin Brown & Burk 150 mg hard capsules
Pregabalin Brown & Burk 200 mg hard capsules
Pregabalin Brown & Burk 225 mg hard capsules
Pregabalin Brown & Burk 300 mg hard capsules
Pregabalin

This is a summary of the Public Assessment Report (PAR) for Pregabalin Brown & Burk 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Pregabalin hard capsules in this lay summary for ease of reading.

For practical information about using Pregabalin hard capsules, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Pregabalin hard capsules and what are they used for?
These applications are for generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised in the United Kingdom (UK) and European Union (EU) called Lyrica 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg hard capsules (Pfizer Europe).

Pregabalin hard capsules are used for the following.

Peripheral and central neuropathic pain:
Pregabalin is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy:
Pregabalin is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation) in adults. The patient's doctor will prescribe Pregabalin to help treat epilepsy when their patient's current treatment is not controlling their condition. Pregabalin should be taken in addition to the patient's current treatment. Pregabalin is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder:
Pregabalin is used to treat Generalised Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty

concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

How do Pregabalin hard capsules work?
Pregabalin hard capsules contain the active ingredient pregabalin, which belongs to a group of medicines called antiepileptics. The way in which pregabalin works is not fully understood. It is thought to work by binding to calcium channels found on cells in the brain and spinal cord. This reduces the release of various natural body chemicals (neurotransmitters) that are stored in nerve cells and that transmit messages between them.

How are Pregabalin hard capsules used?
The pharmaceutical form of these medicines is a hard capsule and the route of administration is oral (by mouth).

The doctor will determine the appropriate dose for their patient.

The dose, which has been adjusted for individual patients and their condition, will generally be between 150 mg and 600 mg each day.

The doctor will tell their patient to take Pregabalin hard capsules either twice or three times a day. For twice a day, Pregabalin hard capsules should be taken once in the morning and once in the evening, at about the same time each day. For three times a day, Pregabalin hard capsules should be taken once in the morning, once in the afternoon and once in the evening, at about the same time each day.

If the effect of the medicine appears to be too strong or too weak, patients should talk to their doctor or pharmacist. Elderly patients (over 65 years of age), take should Pregabalin hard capsules in the same doses as other adults, except if they have problems with their kidneys.

The doctor may prescribe a different dosing schedule and/or dose for patients who have kidney problems.

The capsule should be swallowed whole with water. Patients should continue taking Pregabalin hard capsules until advised to stop by their doctor.

For further information on how Pregabalin hard capsules are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should always take this medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Pregabalin hard capsules have been shown in studies?
Pregabalin hard capsules are generic medicines that fulfil criteria meaning that no additional studies are required. Pregabalin hard capsules have been considered generic medicines of the reference medicines based on a comparison of their physical and chemical characteristics.

What are the possible side effects of Pregabalin hard capsules?

For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicines. Patients can also report suspected side effects themselves, or a report can be made on behalf of someone else they care for, directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of these medicines.

Because Pregabalin hard capsules are generic medicines, their benefits and possible side effects are considered to be the same as for the reference medicines.

Why were Pregabalin hard capsules approved?
It was concluded that, Pregabalin hard capsules has been shown to be comparable to the reference medicines. Therefore, the MHRA decided that, as for the reference medicines, the benefits are greater than the risks and recommended that they can be approved for use.

What measures are being taken to ensure the safe and effective use of Pregabalin hard capsules?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Pregabalin hard capsules The RMP details the important risks of Pregabalin hard capsules, how these risks can be minimised, any uncertainties about Pregabalin hard capsules (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Pregabalin hard capsules:
Important identified risks:

- dizziness, somnolence, loss of consciousness, syncope, and potential for accidental injury
- Discontinuation events
- Drug interactions (lorazepam, ethanol, and central nervous system depressants)
- Euphoria
- Congestive heart failure
- Vision-related events
- Abuse and drug dependence

Important potential risks:

- Suicidality
- Off-label use in paediatric patients

Missing information:

- Pregnancy and lactating women

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Pregabalin hard capsules are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

Other information about Pregabalin hard capsules

Marketing Authorisations for Pregabalin hard capsules were granted in the United Kingdom (UK) on 24 January 2022.

The full PAR for Pregabalin hard capsules follows this summary.

This summary was last updated in March 2022.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Pregabalin Brown & Burk 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225mg and 300 mg hard capsules (PL 25298/0292-0299) could be approved.

The products are approved for the following indications:
Neuropathic pain
For the treatment of peripheral and central neuropathic pain in adults.

Epilepsy
As adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder
For the treatment of Generalised Anxiety Disorder (GAD) in adults.

The active substance, pregabalin, is a gamma-aminobutyric acid analogue [(S)-3-(aminomethyl)-5-methylhexanoic acid]. Pregabalin binds to an auxiliary subunit (α2- δ protein) of voltage-gated calcium channels in the central nervous system.

These applications were approved under Regulation 51B of The Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended), as generic medicines of suitable originator medicinal products, Lyrica 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg hard capsules, that have been licensed within the UK for a suitable time, in line with the legal requirements.

No new non-clinical studies were conducted, which is acceptable given that the applications are for generic medicinal products of suitable reference products.

A biowaiver was submitted with these applications, which was accepted. No bioequivalence study was required and no new clinical studies were provided with these applications.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

National marketing authorisations were granted in the United Kingdom (UK) on 24 January 2022.

II QUALITY ASPECTS

II.1 Introduction

These products consist of hard capsules containing either 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg of pregabalin.

In addition to pregabalin, these products also contain the following excipients:
Capsule content:
Lactose monohydrate
Pregelatinised starch
Talc

Capsule shell:
Gelatin
Titanium dioxide (E171)
Iron oxide red (E172) (with exception of 50 mg and 150 mg strengths)
Sodium laurilsulphate
Purified water

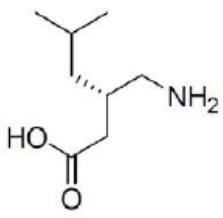
Printing ink:
Shellac (E904)
Dehydrated alcohol (E1510)
Isopropyl alcohol
Butyl alcohol
Propylene glycol (E1520)
Strong Ammonia solution (E527)
Black iron oxide (E172)
Potassium hydroxide (E525)
Purified water

The finished products are packaged in clear aluminium/polyvinyl chloride blister packs in pack sizes of 7, 10, 14, 20, 21, 28, 30, 35, 40, 42, 49, 50, 56, 60, 63, 70, 77, 80, 84, 90, 91, 98, 100 and 112 hard capsules. The 25 mg strength are also available in pack sizes of 120, 150, 168, 200 and 500 hard capsules. Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

II.2 ACTIVE SUBSTANCE

rINN: **Pregabalin**
Chemical Name: (3*S*)-3-(Aminomethyl)-5-methylhexanoic acid
Molecular Formula: $C_8H_{17}NO_2$
Chemical Structure:



Molecular Weight: 159.23

Appearance:	White or almost white crystalline powder
Solubility:	Sparingly soluble in water, slightly soluble in methanol and practically insoluble in heptane.

Pregabalin is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3 DRUG PRODUCTS

Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

Comparative *in vitro* dissolution profiles have been provided for the proposed and reference products.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients.

With the exception of lactose and gelatin, no excipients of animal or human origin are used in the final products.

The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption. EDQM certificates of suitability have been provided for the gelatin.

These products do not contain or consist of genetically modified organisms (GMO).

Manufacture of the products

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

Finished Product Specifications

The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

Stability

Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of 2 years with no special storage conditions, is acceptable.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of Marketing Authorisations is recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of pregabalin are well-known, no new non-clinical studies are required, and none have been provided. An overview based on the literature review is, thus, appropriate.

III.2 Pharmacology
No new pharmacology data were provided, and none were required for these applications.

III.3 Pharmacokinetics
No new pharmacokinetic data were provided, and none were required for these applications.

III.4 Toxicology
No new toxicology data were provided, and none were required for these applications.

III.5 Ecotoxicity/Environmental Risk Assessment
Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the applications are for generic version) of already authorised products, an increase in environmental exposure is not anticipated following approval of the Marketing Authorisations for the proposed products.

III.6 Discussion on the non-clinical aspects
The grant of Marketing Authorisations is recommended.

IV CLINICAL ASPECTS

IV.1 Introduction
The clinical pharmacology, efficacy and safety of pregabalin are well-known. According to the regulatory requirements, the applicant has provided a suitable biowaiver and a bioequivalence study is not required for these products. An overview based on a literature review is, thus, satisfactory.

IV. 2 Pharmacokinetics
No new pharmacokinetic data have been submitted for these applications and none were required.

IV.3 Pharmacodynamics
No new pharmacodynamic data have been submitted for these applications and none were required.

IV.4 Clinical efficacy
No new efficacy data were submitted with these applications and none were required.

IV.5 Clinical safety
No new safety data were submitted with these applications and none were required. The safety profile for these products is considered to be the same as Lyrica 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg hard capsules.

IV.6 Risk Management Plan (RMP)

The applicant has submitted ~~a~~an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

IV.7 Discussion on the clinical aspects

The grant of Marketing Authorisations is recommended for these applications.

V USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Atorvastatin 10 mg, 20 mg, 40 mg and 80 mg film-coated tablets (PL 25298/0160-0163; Brown & Burk UK Limited) for the format, design, and layout and Lyrica 25 mg, 50 mg, 75mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules (PLGB 50622/0068-76; Upjohn UK Limited) for text and key safety messages. The bridging report submitted by the applicant is acceptable.

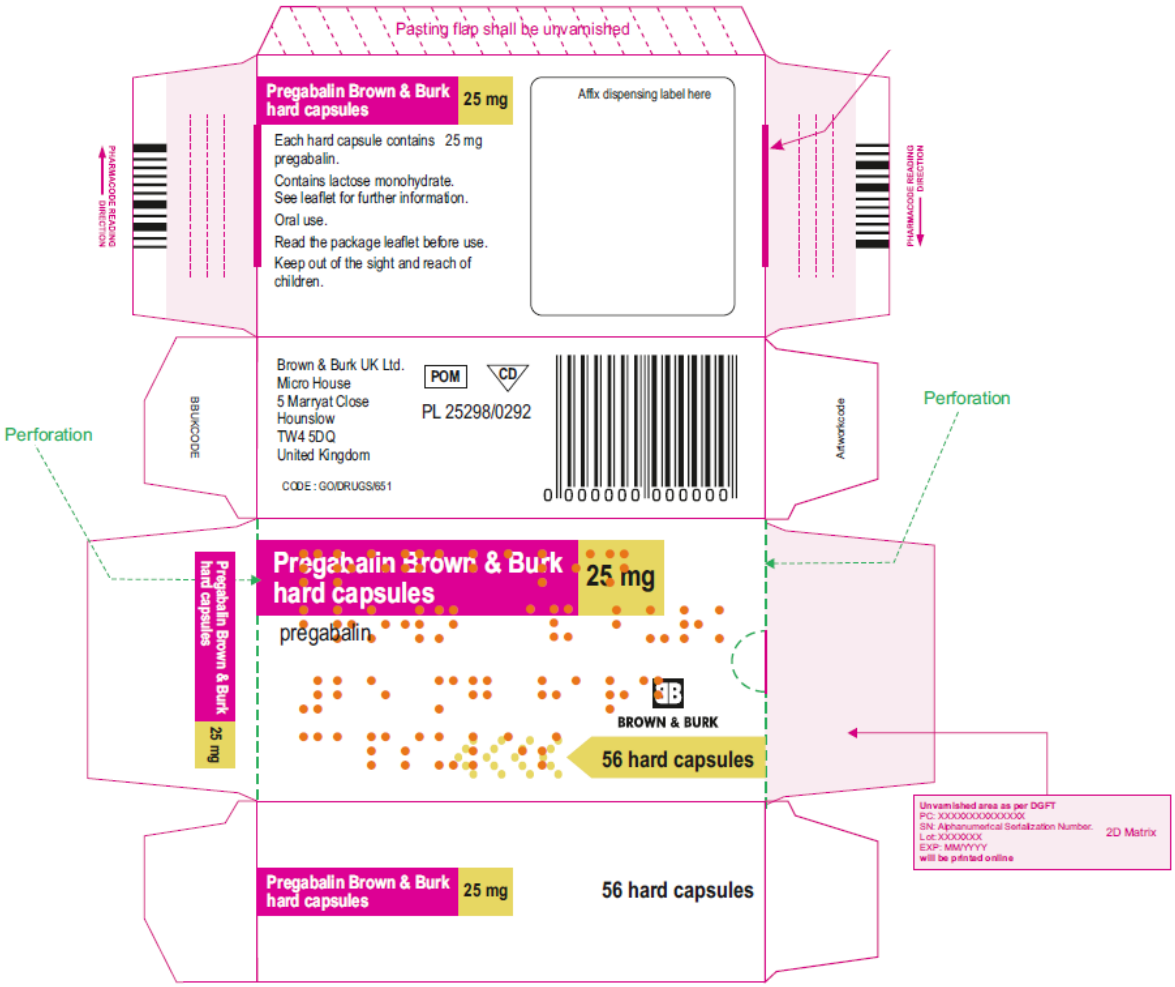
VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

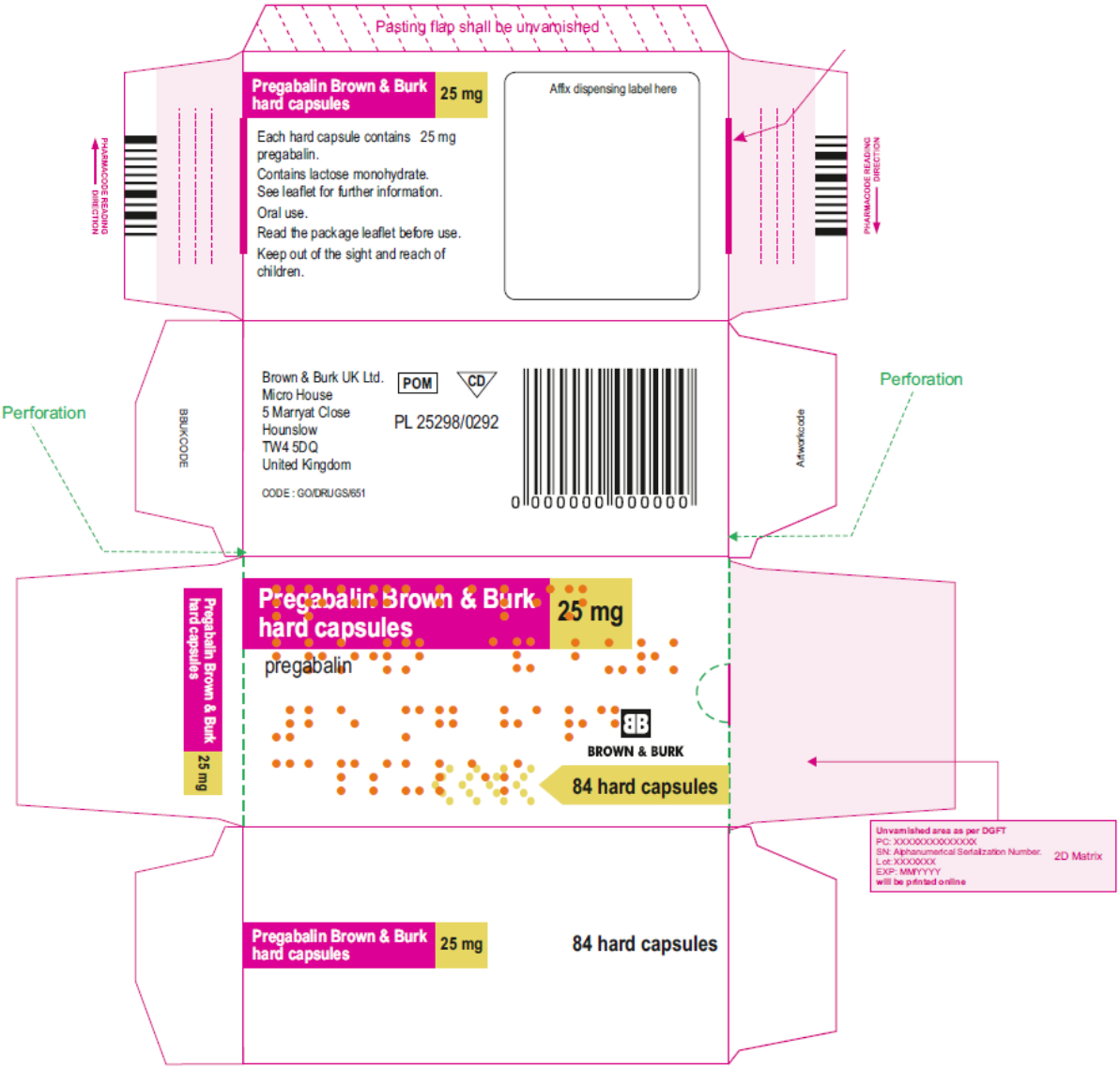
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with pregabalin is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the reference products.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

Representative copies of the labels at the time of licensing are provided below.


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
25 mg
Each hard capsule contains 25 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0292
BBUKCODE
Artworkcode
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
25 mg
pregabalin
BROWN & BURK
56 hard capsules
Unvarnished area as per DGFT
PO: XXXXXXXXXXXXXX
SN: Alphanumerical Serialization Number
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
25 mg
56 hard capsules


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
25 mg
Each hard capsule contains 25 mg pregabalin.
Contains lactose monohydrate.
See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
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TW4 5DQ
United Kingdom
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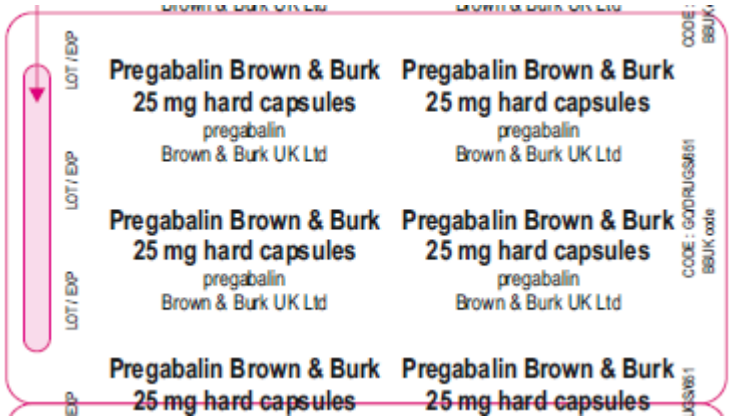
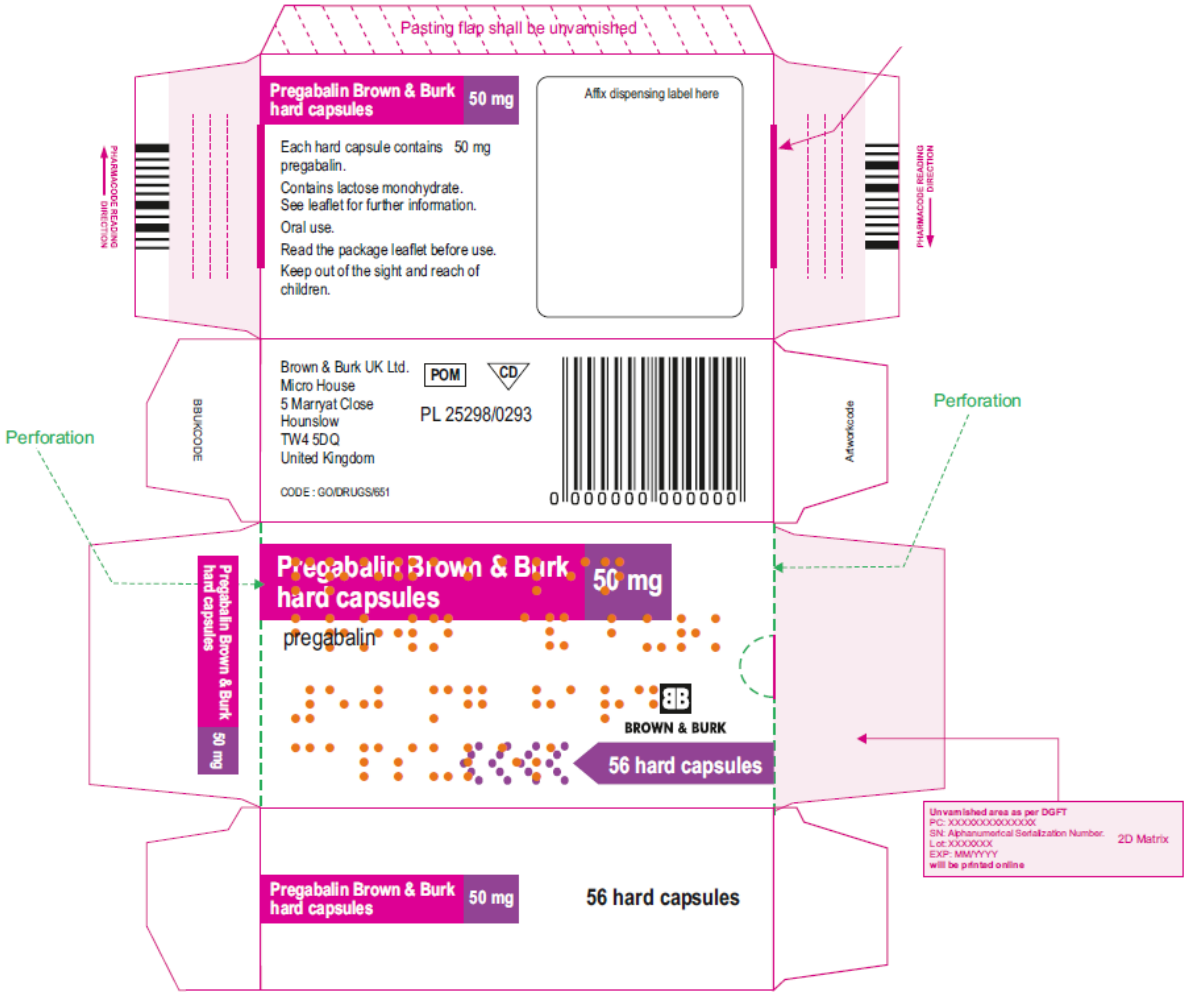
POM
CD
PL 25298/0292
BBUKCODE
Artworkcode
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
25 mg
pregabalin
BROWN & BURK
84 hard capsules
Unvarnished area as per DGFT
PC: XXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
25 mg
84 hard capsules


LOT / EXP
Pregabalin Brown & Burk
25 mg hard capsules
pregabalin
Brown & Burk UK Ltd
CODE : GO/DRUGS/651
BBUK code


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
50 mg
Affix dispensing label here
Each hard capsule contains 50 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
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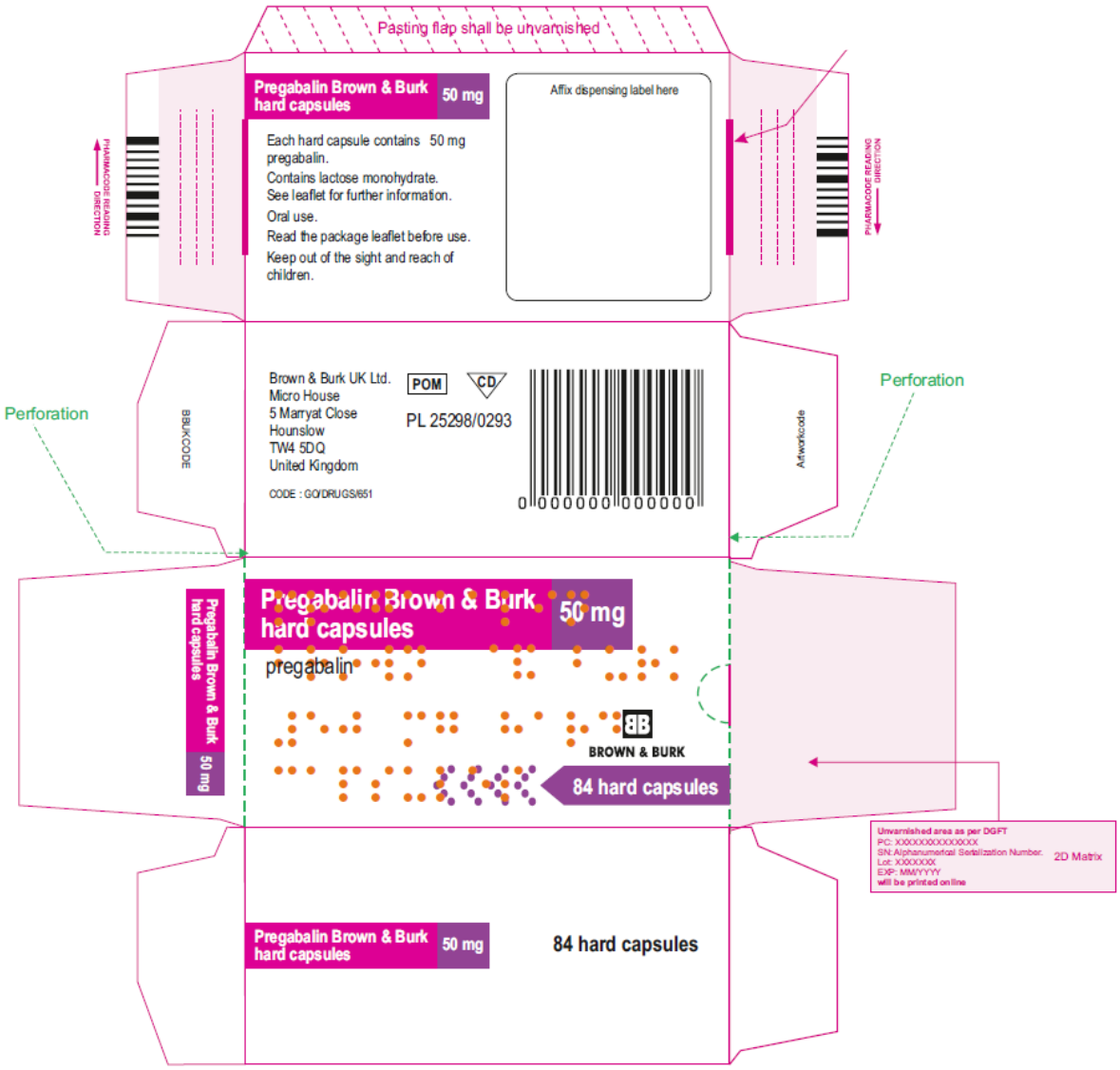
SN: Alphanumerical Serialization Number.
Lot:XXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
50 mg
56 hard capsules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Pregabalin Brown & Burk hard capsules 50 mg
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Each hard capsule contains 50 mg pregabalin.
Contains lactose monohydrate.
See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
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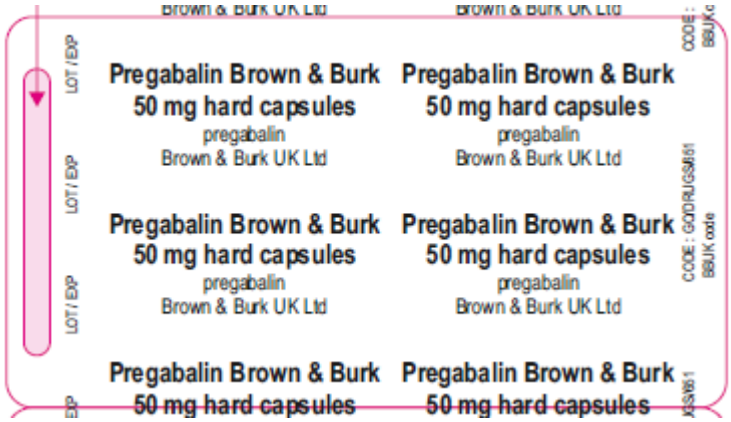
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules 50 mg
84 hard capsules


Brown & Burk UK Ltd
Brown & Burk UK Ltd
LOT / EXP
LOT / EXP
LOT / EXP
Pregabalin Brown & Burk 50 mg hard capsules
pregabalin
Brown & Burk UK Ltd
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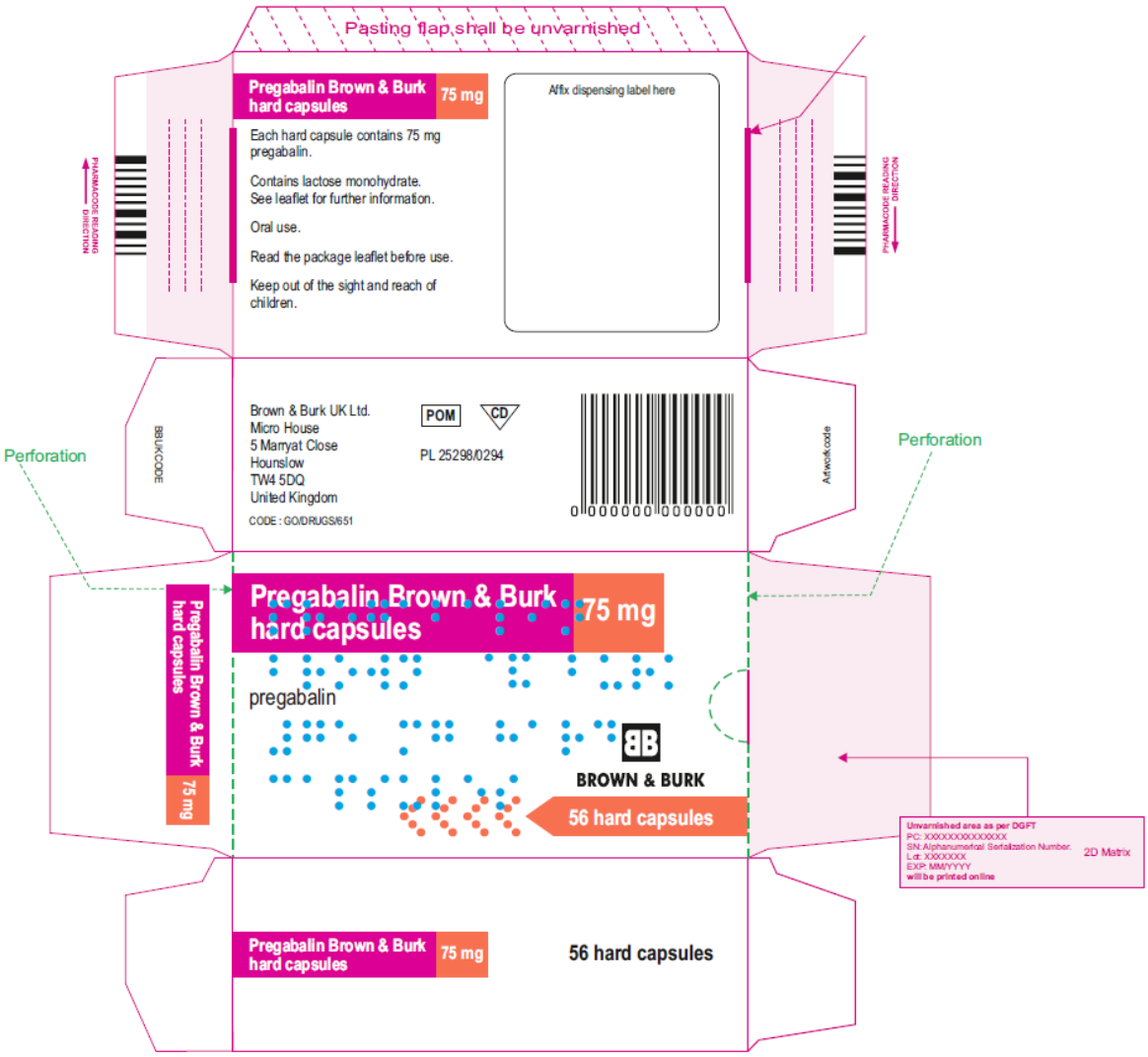
Brown & Burk UK Ltd
Pregabalin Brown & Burk 50 mg hard capsules
Pregabalin Brown & Burk 50 mg hard capsules
CODE : GO/DRUGS/651
BBUK code


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
75 mg
Each hard capsule contains 75 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
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TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
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pregabalin
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56 hard capsules
Unvarnished area as per DGFT
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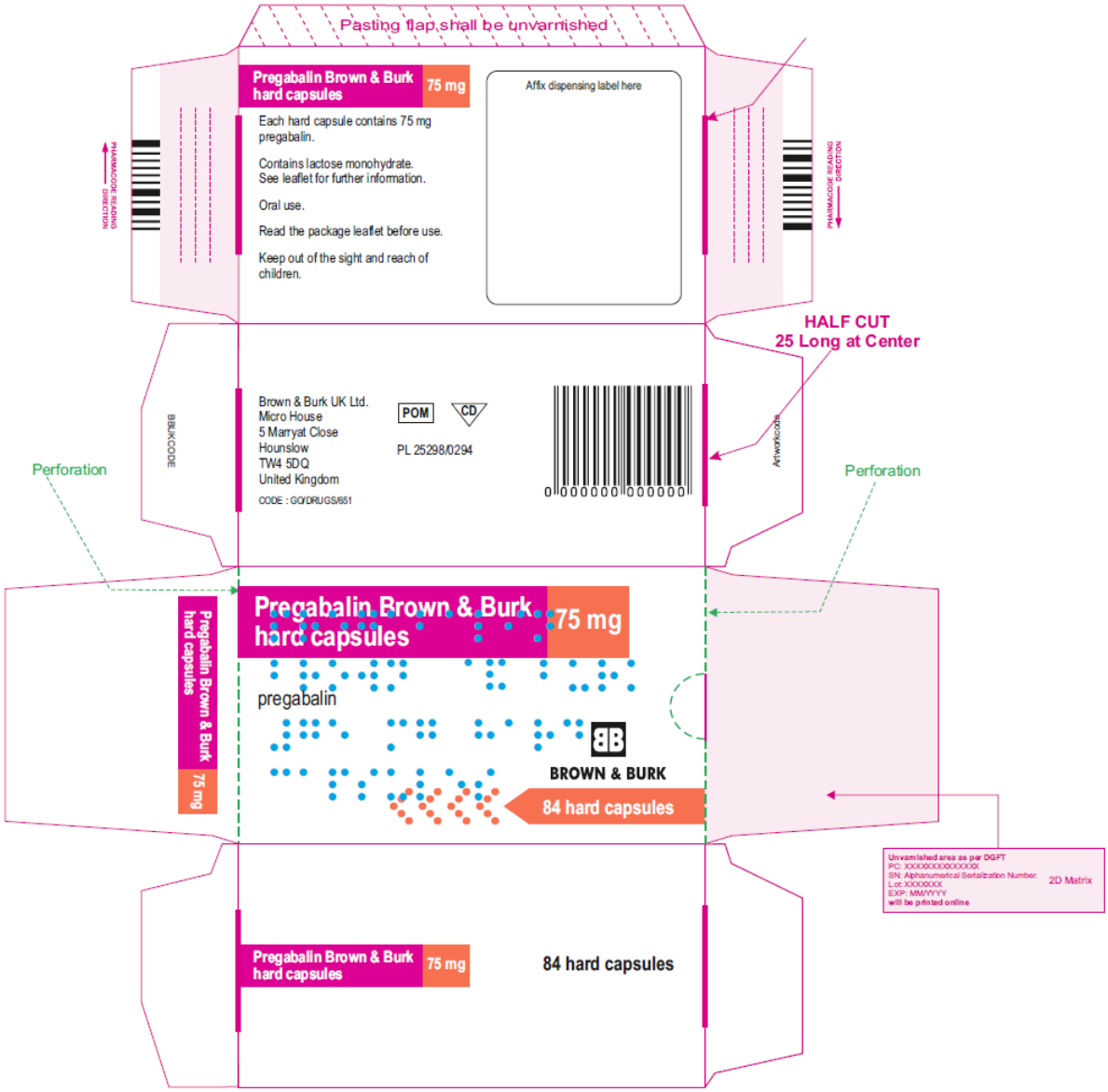
SN: Alphanumerical Serialization Number.
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
75 mg
56 hard capsules


Pasting flap shall be unvarnished
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75 mg
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Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
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Affix dispensing label here
PHARMACODE READING DIRECTION
HALF CUT
25 Long at Center
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0294
BBUKCODE
Artworkcode
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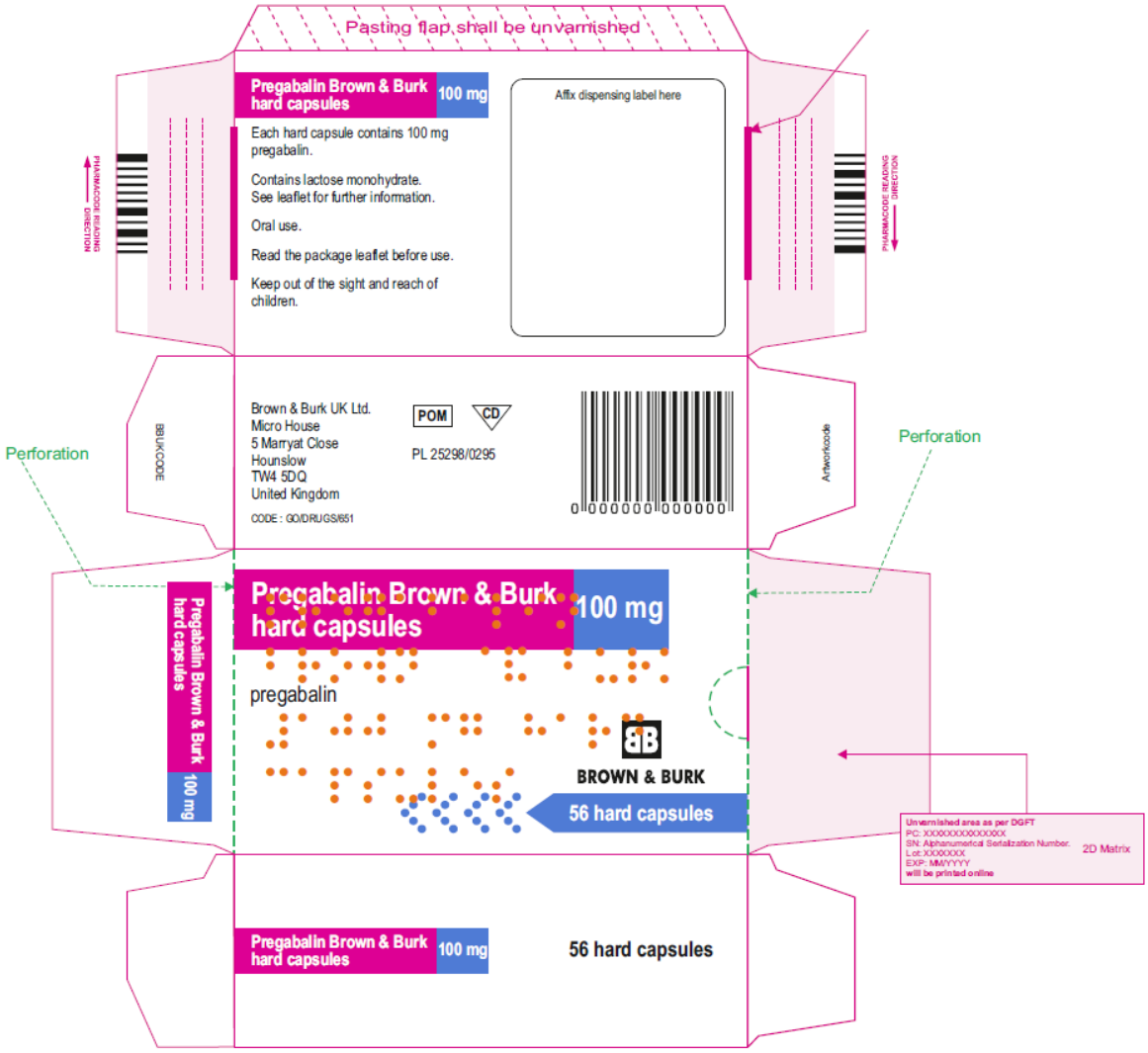
will be printed online
2D Matrix
84 hard capsules


Brown & Burk UK Ltd
Pregabalin Brown & Burk 75 mg hard capsules
pregabalin
Brown & Burk UK Ltd
CODE : GO/DRUGS/651
BBUKCODE


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
100 mg
Each hard capsule contains 100 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
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United Kingdom
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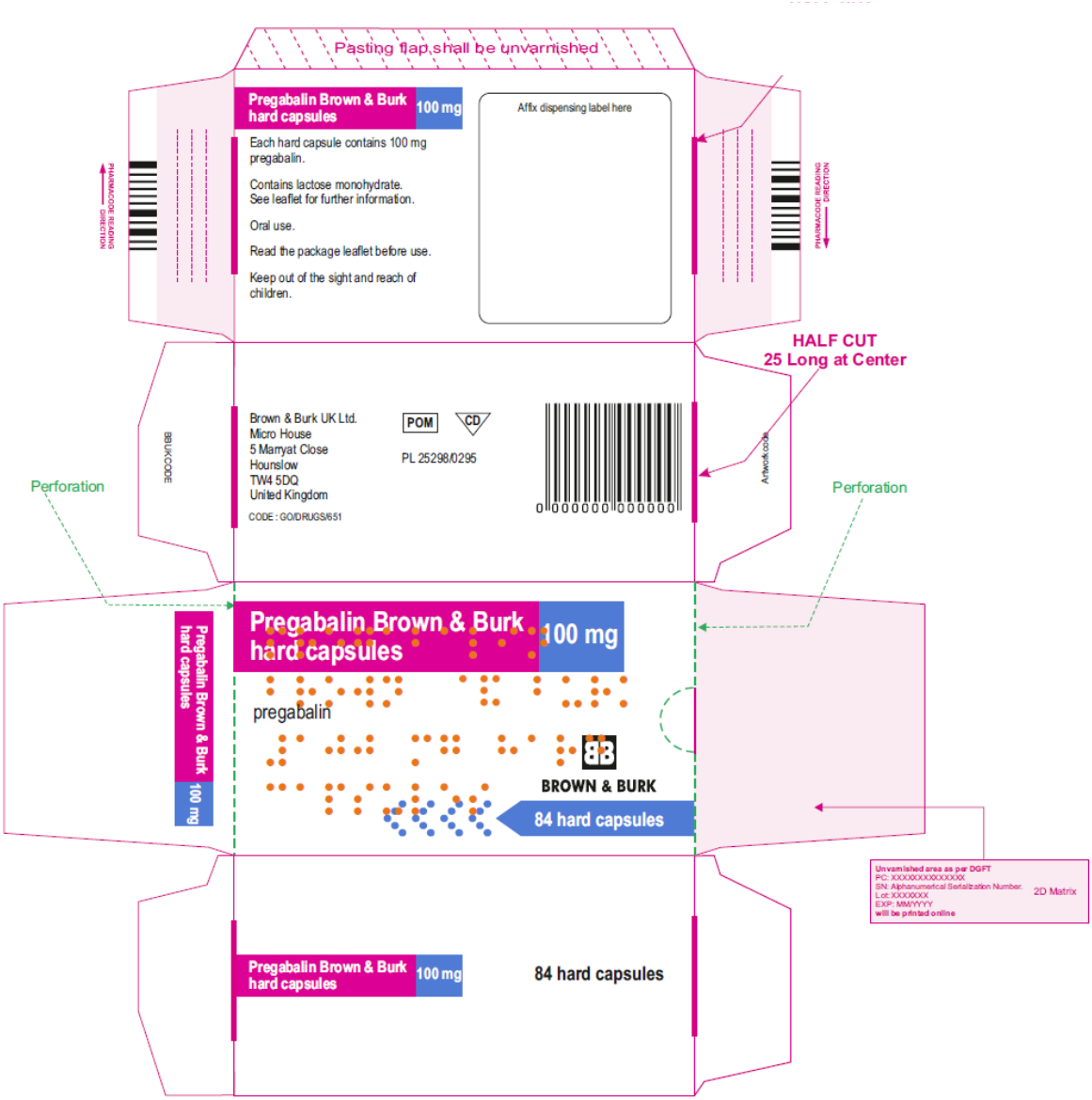
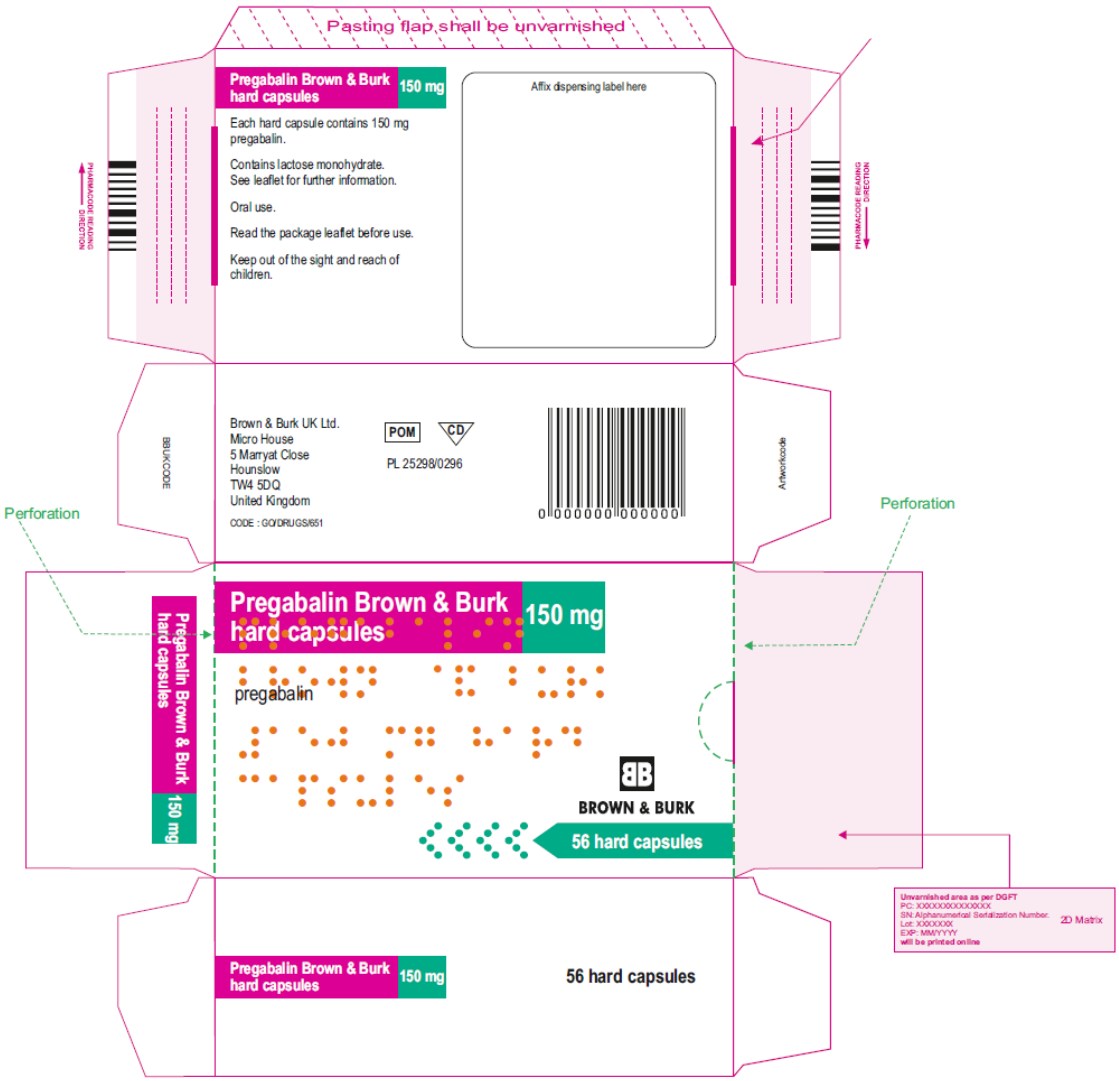
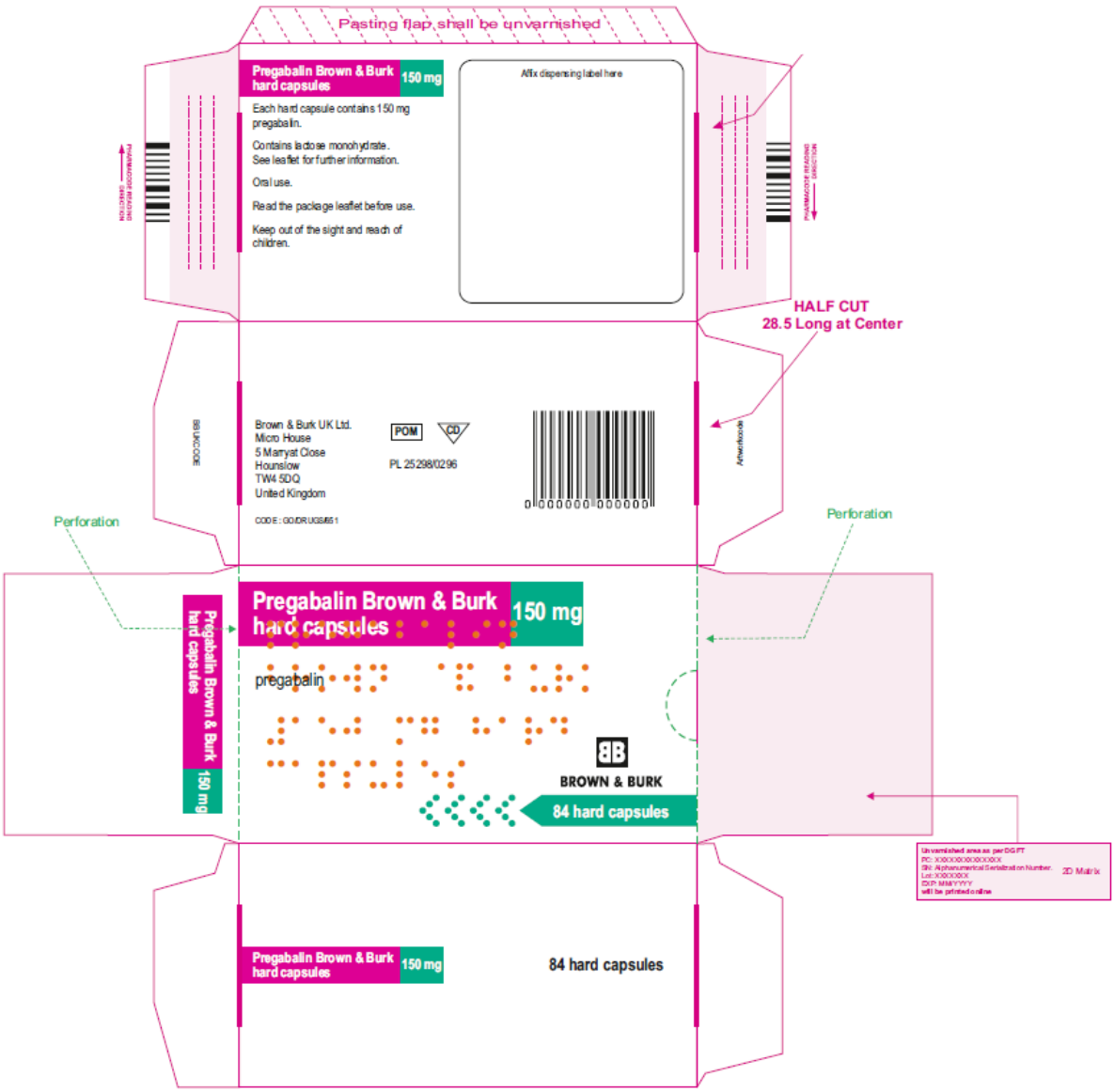
100 mg
56 hard capsules

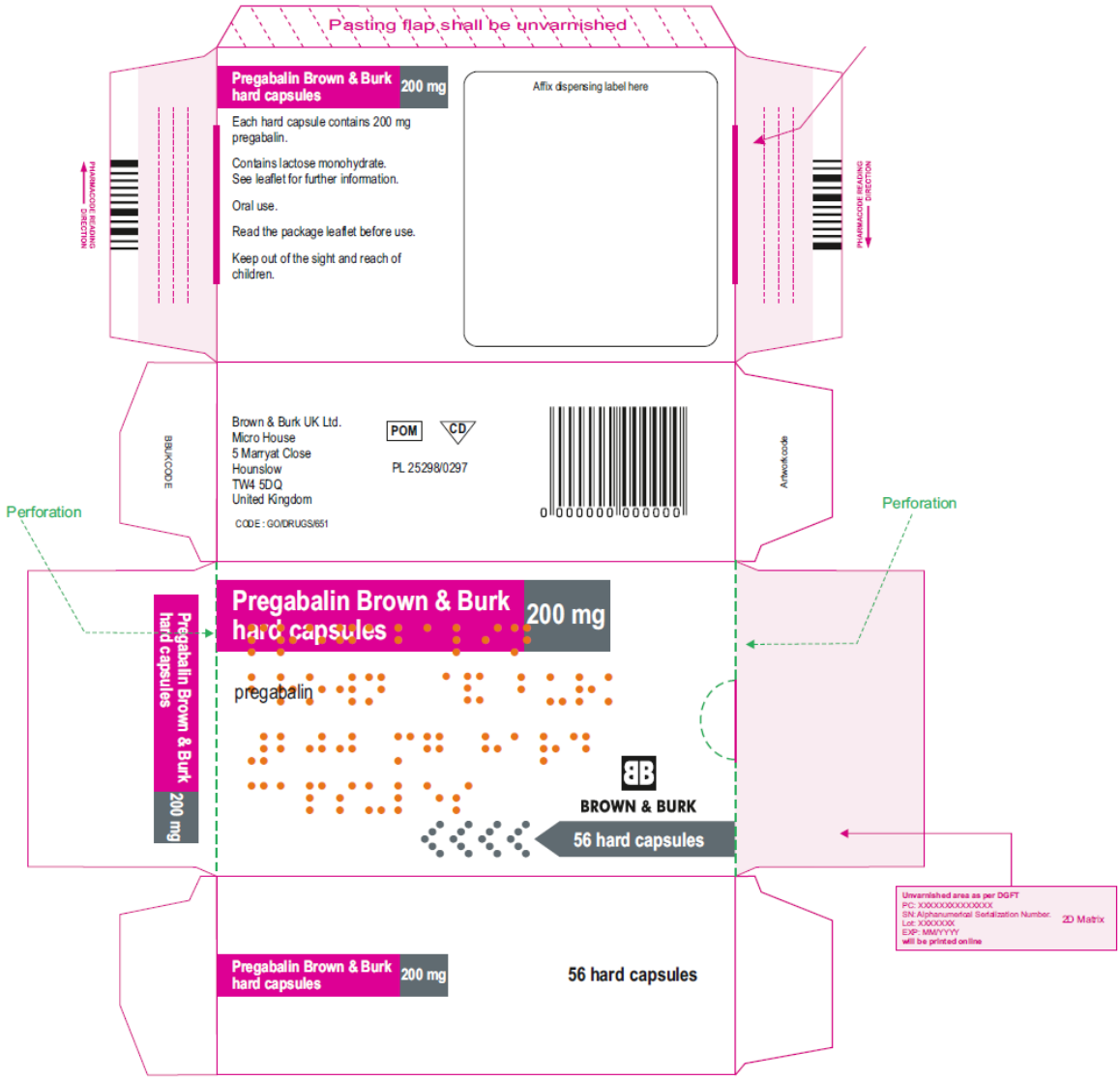

Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
100 mg
Each hard capsule contains 100 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
HALF CUT
25 Long at Center
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0295
BBUKCODE
Artwork code
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
100 mg
pregabalin
BROWN & BURK
84 hard capsules
Unvarnished area as per DGFT
PC: XXXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
100 mg
84 hard capsules

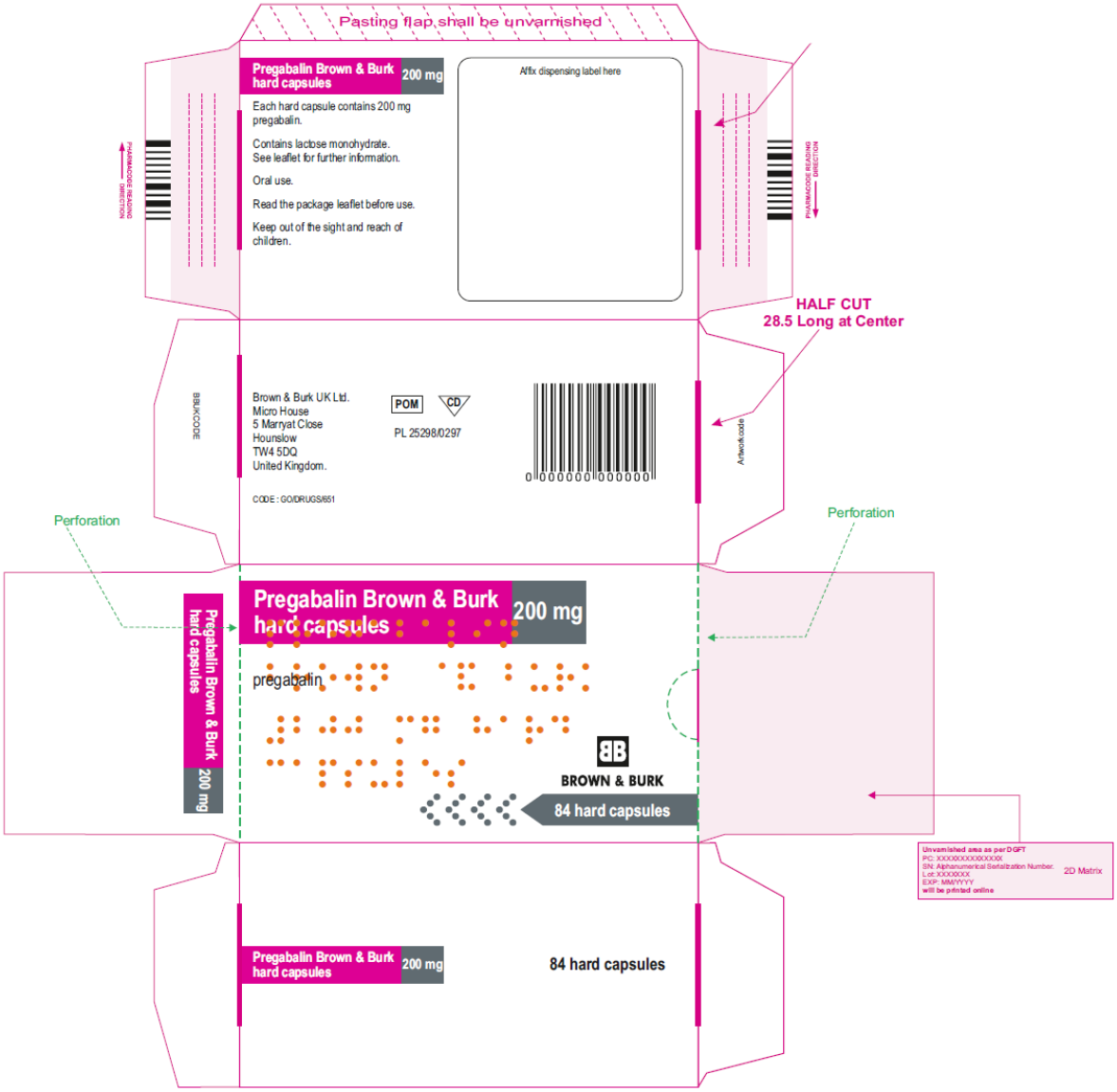

Brown & Burk UK Ltd
Brown & Burk UK Ltd
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
Brown & Burk UK Ltd
CODE : GO/DRUGS/651
BBUKCODE
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
Brown & Burk UK Ltd
CODE : GO/DRUGS/651
BBUKCODE
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
Pregabalin Brown & Burk 100 mg hard capsules
pregabalin
BBUKCODE


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
150 mg
Each hard capsule contains 150 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0296
0 000000 000000
BBUKCODE
Artworkcode
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
150 mg
pregabalin
BROWN & BURK
56 hard capsules
Unvarnished area as per DGFT
PC: XXXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules
150 mg
56 hard capsules

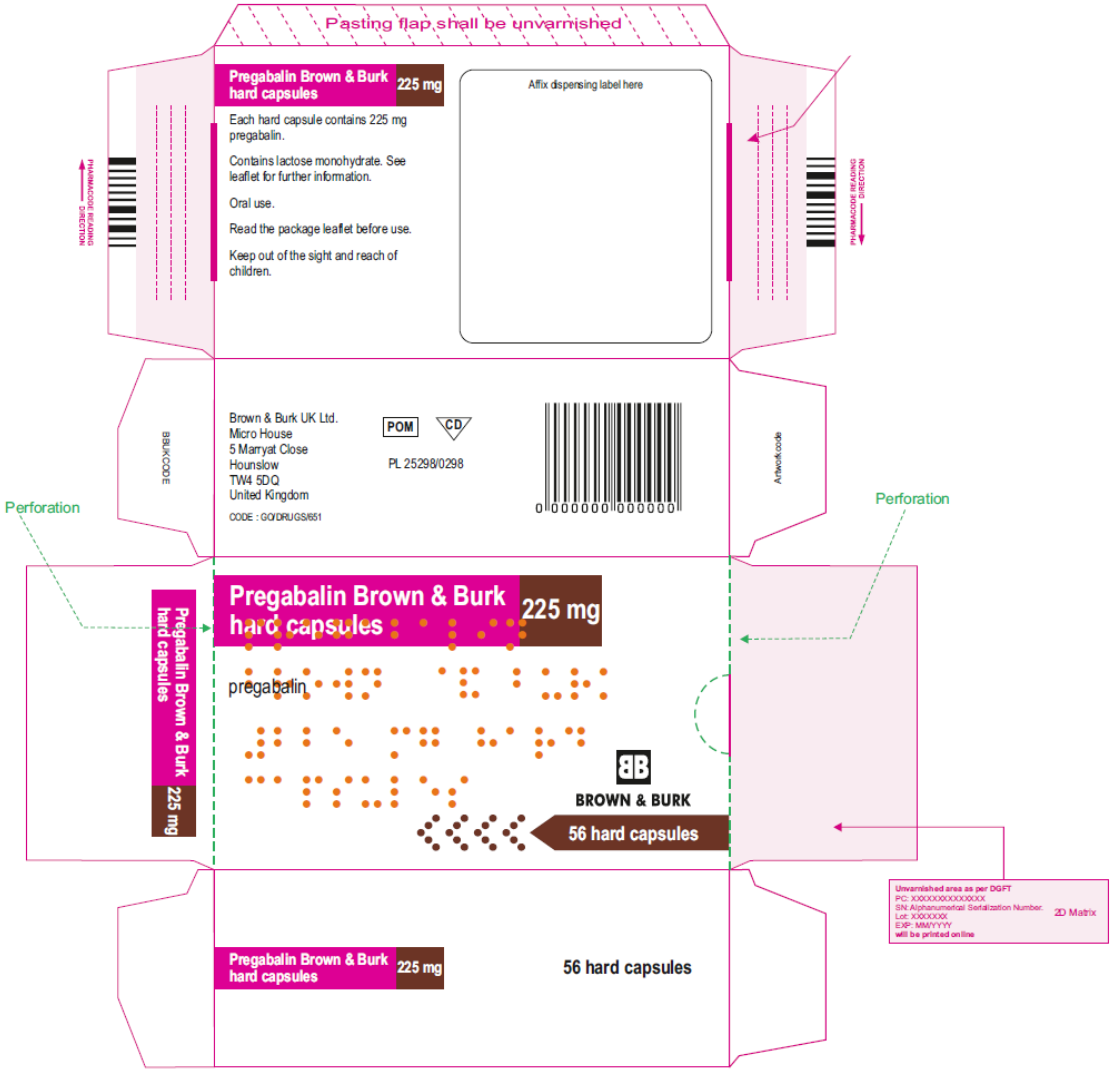

Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
150 mg
Each hard capsule contains 150 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
HALF CUT
28.5 Long at Center
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
POM
CD
PL 25298/0296
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
150 mg
pregabalin
BROWN & BURK
84 hard capsules
Pregabalin Brown & Burk hard capsules
150 mg
84 hard capsules

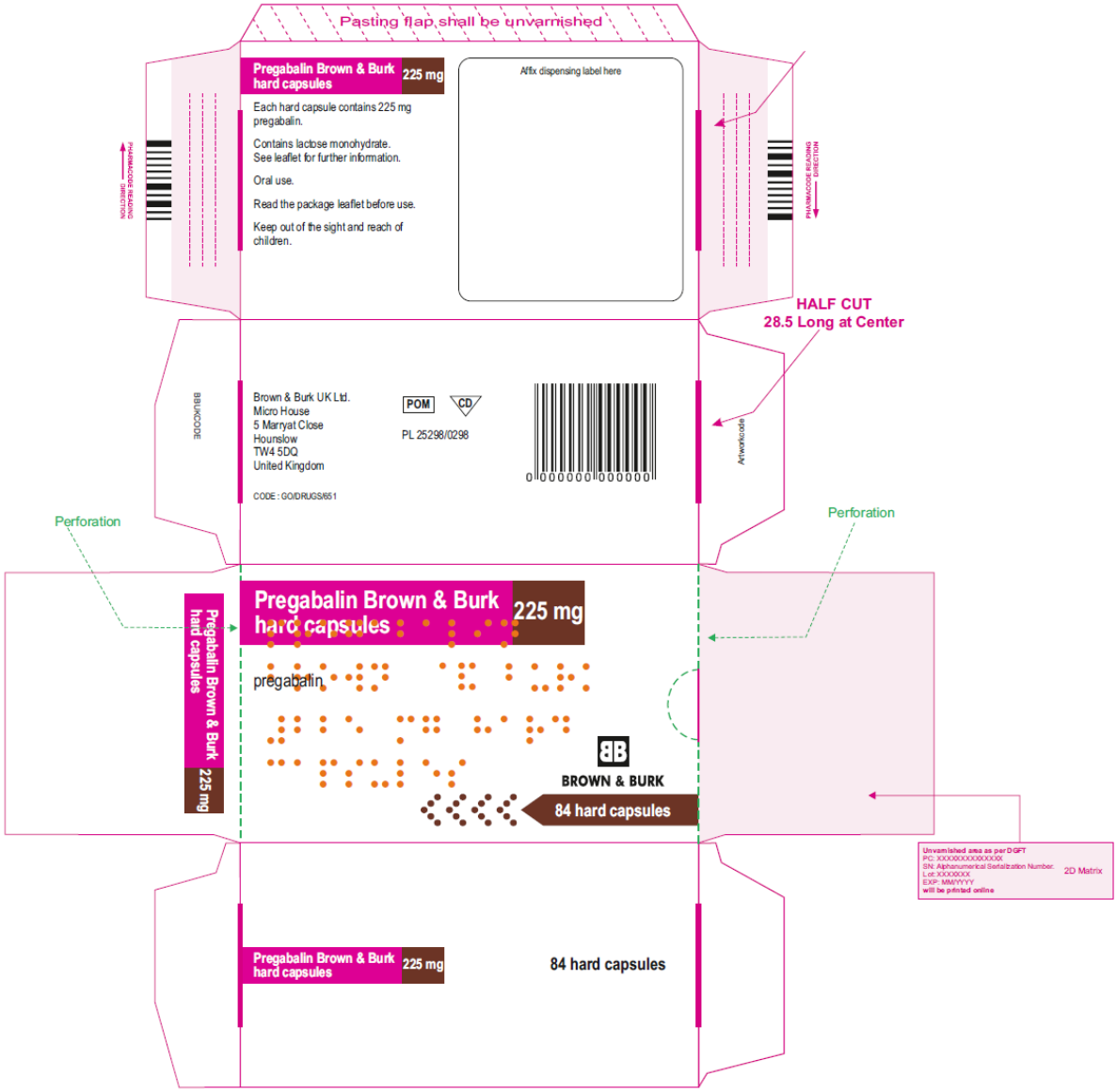

pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk
150 mg hard capsules
pregabalin
Brown & Burk UK Ltd


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules 200 mg
Each hard capsule contains 200 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0297
BBUKCODE
Artwork code
Perforation
Perforation
Pregabalin Brown & Burk hard capsules 200 mg
pregabalin
BROWN & BURK
56 hard capsules
Unvarnished area as per DGFT
PC: XXXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Pregabalin Brown & Burk hard capsules 200 mg
56 hard capsules

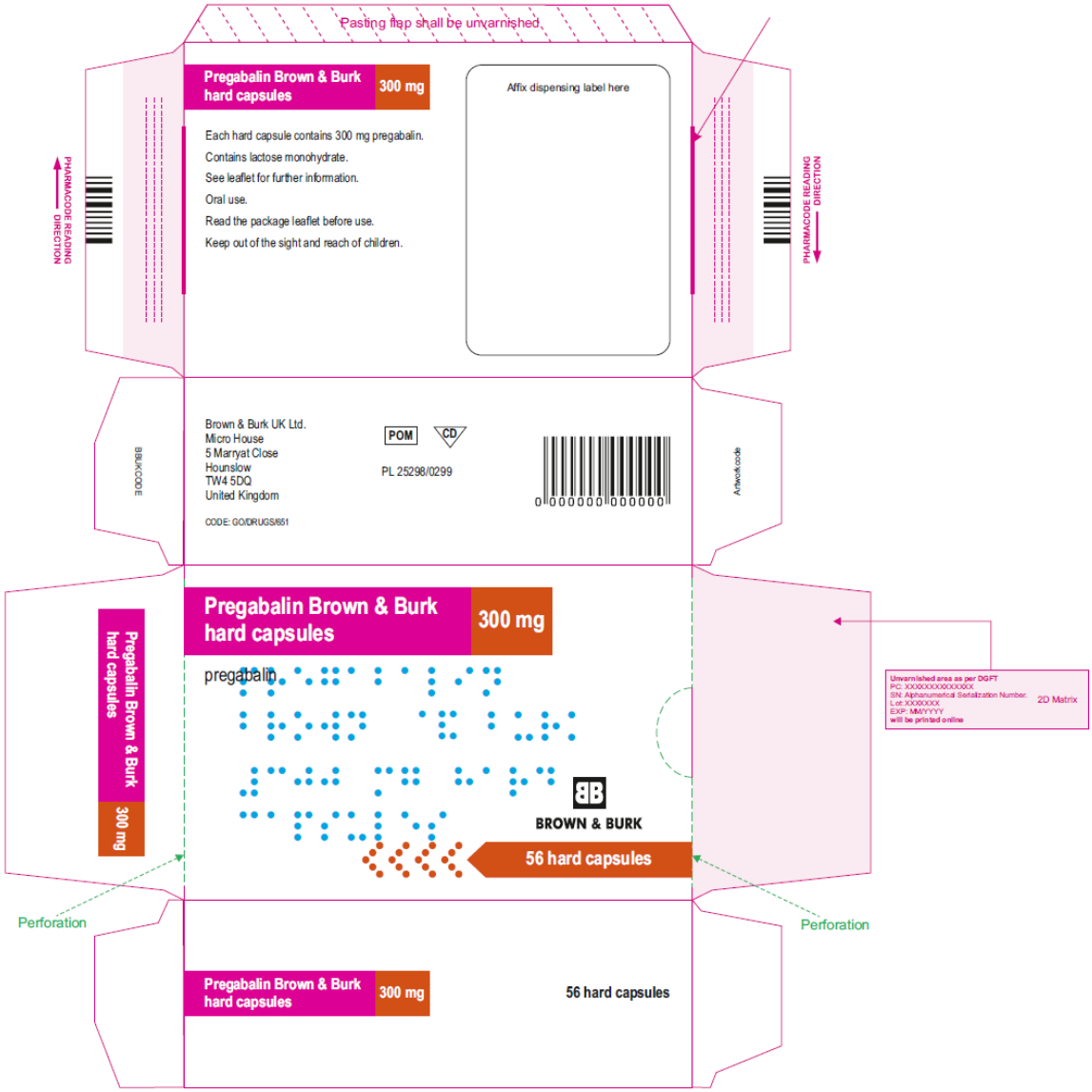

Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
200 mg
Each hard capsule contains 200 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
HALF CUT
28.5 Long at Center
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom.
POM
CD
PL 25298/0297
CODE : GO/DRUGS/651
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
200 mg
pregabalin
BROWN & BURK
84 hard capsules
Unvarnished area as per DGFT
2D Matrix
Pregabalin Brown & Burk hard capsules
200 mg
84 hard capsules

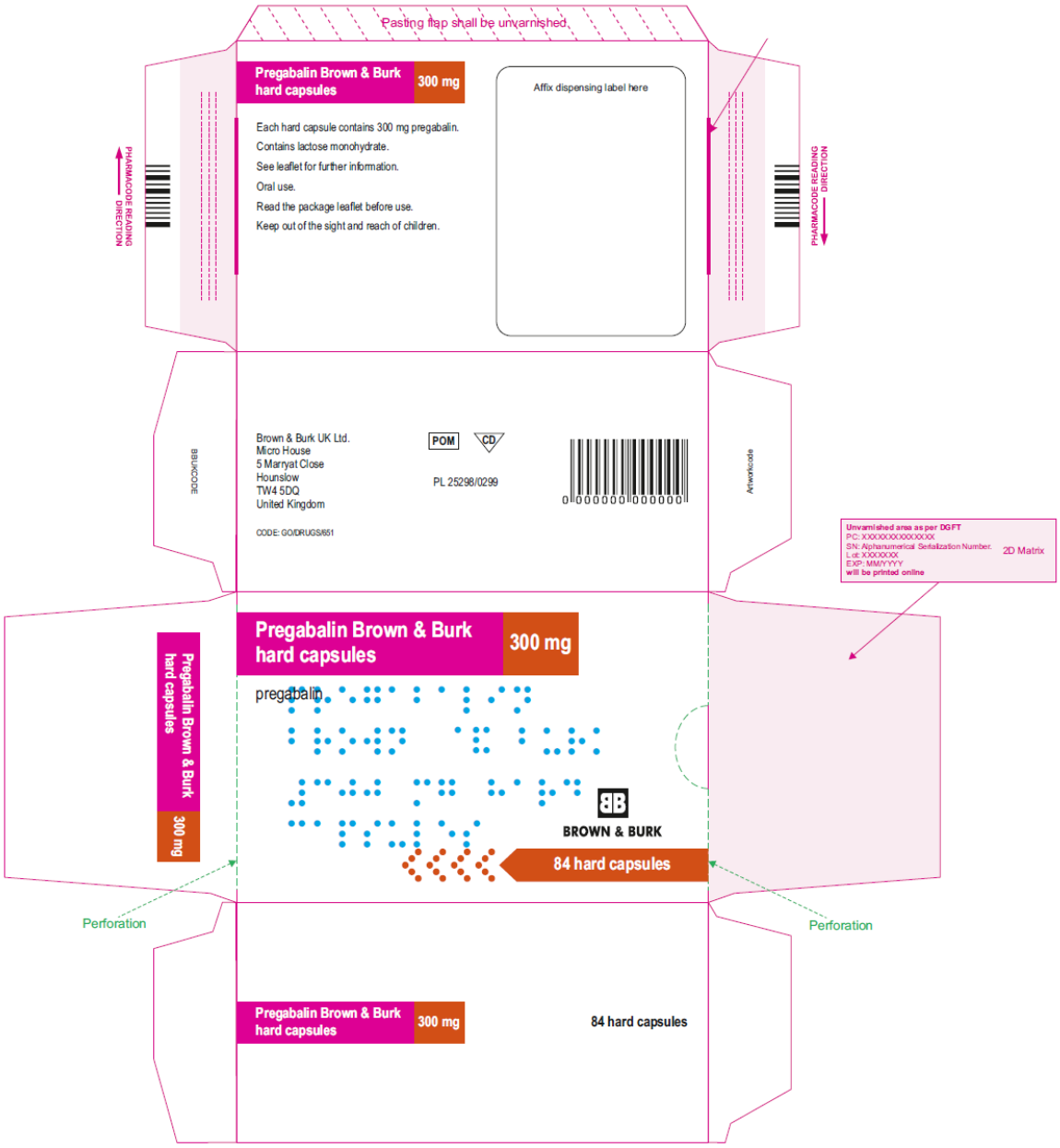

pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk
200 mg hard capsules
pregabalin
Brown & Burk UK Ltd


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules 225 mg
Each hard capsule contains 225 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE : GO/DRUGS/651
POM
CD
PL 25298/0298
Perforation
Perforation
Pregabalin Brown & Burk hard capsules 225 mg
pregabalin
BROWN & BURK
56 hard capsules
Unwarnished area as per DGFT
2D Matrix
Pregabalin Brown & Burk hard capsules 225 mg
56 hard capsules


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules 225 mg
Affix dispensing label here
Each hard capsule contains 225 mg pregabalin.
Contains lactose monohydrate. See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
PHARMACODE READING DIRECTION
HALF CUT
28.5 Long at Center
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
POM
CD
PL 25298/0298
CODE : GO/DRUGS/651
BBUKCODE
Artworkcode
Perforation
Perforation
Pregabalin Brown & Burk hard capsules 225 mg
pregabalin
BROWN & BURK
84 hard capsules
Unvarnished area as per DGFT
2D Matrix
Pregabalin Brown & Burk hard capsules 225 mg
84 hard capsules


pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk 225 mg hard capsules
pregabalin
Brown & Burk UK Ltd
CODE : GO/DRUGS/651
BBUKCODE


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
300 mg
Each hard capsule contains 300 mg pregabalin.
Contains lactose monohydrate.
See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Affix dispensing label here
PHARMACODE READING DIRECTION
PHARMACODE READING DIRECTION
BBUKCODE
Artwork code
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE: GO/DRUGS/651
POM
CD
PL 25298/0299
0 000000 000000
Pregabalin Brown & Burk hard capsules
300 mg
pregabalin
BROWN & BURK
56 hard capsules
Unvarnished area as per DGFT
PC: XXXXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
Perforation
Perforation
Pregabalin Brown & Burk hard capsules
300 mg
56 hard capsules


Pasting flap shall be unvarnished
Pregabalin Brown & Burk hard capsules
300 mg
Affix dispensing label here
Each hard capsule contains 300 mg pregabalin.
Contains lactose monohydrate.
See leaflet for further information.
Oral use.
Read the package leaflet before use.
Keep out of the sight and reach of children.
PHARMACODE READING DIRECTION
Brown & Burk UK Ltd.
Micro House
5 Marryat Close
Hounslow
TW4 5DQ
United Kingdom
CODE: GO/DRUGS/651
POM
CD
PL 25298/0299
Artworkcode
Unvarnished area as per DGFT
PC: XXXXXXXXXXXX
SN: Alphanumerical Serialization Number.
Lot: XXXXXX
EXP: MM/YYYY
will be printed online
2D Matrix
pregabalin
BROWN & BURK
84 hard capsules
Perforation
Perforation
84 hard capsules


pregabalin
Brown & Burk UK Ltd
Pregabalin Brown & Burk
300 mg hard capsules
CODE : GO/DRUGS/651
BBUKCODE

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**