Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Pregabalin Amneal 25 mg hard capsules
Pregabalin Amneal 50 mg hard capsules
Pregabalin Amneal 75 mg hard capsules
Pregabalin Amneal 100 mg hard capsules
Pregabalin Amneal 150mg hard capsules
Pregabalin Amneal 200mg hard capsules
Pregabalin Amneal 225mg hard capsules
Pregabalin Amneal 300 mg hard capsules

(pregabalin)

PL 42357/0286-0293

Amneal Pharma Europe Ltd

LAY SUMMARY

Pregabalin Amneal 25 mg, 50 mg, 75 mg, 100 mg, 150mg, 200mg, 225mg, and 300 mg hard capsules

(pregabalin)

This is a summary of the Public Assessment Report (PAR) for Pregabalin Amneal Hard Capsules. It explains how Pregabalin Amneal Hard Capsules 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 Pregabalin Amneal Hard Capsules.

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 package leaflet 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 are considered interchangeable with, reference medicines already authorised in the European Union (EU) called Lyrica hard capsules 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, and 300mg.

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 Capsules contains 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 this medicine is a hard capsule and the route of administration is by mouth (oral).

The doctor will determine what dose is appropriate for their patient. Pregabalin is for oral use only.

Use in peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:

- The doctor will instruct their patient regarding the number of capsules to take.
- The dose, which has been adjusted for individual patients and their condition, will generally be between 150 mg and 600mg each day.
- The doctor will tell their patient to take Pregabalin either twice or three times a day. For twice a day Pregabalin 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 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 Pregabalin appears to be too strong or too weak, patients should talk to their doctor or pharmacist. Elderly patients (over 65 years of age), take Pregabalin in the same doses as other adults except if they have problems with 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 until advised to stop by their doctor.

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

This medicine can only be obtained with a prescription. The patient should always take this medicine exactly as their doctor 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?
Because Pregabalin hard capsules are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

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

For the full list of all side effects reported with this medicine, see Section 4 of the package leaflet or the Summaries of Product Characteristics (SmPC) available on the MHRA website.

Why was Pregabalin hard capsules approved?
It was concluded that, in accordance with EU requirements, Pregabalin hard capsules has been shown to be comparable to and to be bioequivalent to the reference medicines. Therefore, the MHRA decided that, as for the reference medicines, the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pregabalin hard capsules?
A Risk Management Plan (RMP) has been developed to ensure that Pregabalin hard capsules is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Pregabalin hard capsules
Marketing Authorisations for Pregabalin hard capsules were granted in the UK on 3 May 2019 issue of the Marketing Authorisations.

The full PAR for Pregabalin hard capsules follows this summary.

This summary was last updated in June 2019.

TABLE OF CONTENTS

Contents

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 Amneal 25 mg, 50 mg, 75 mg, 100 mg, 150mg, 200mg, 225mg, and 300 mg hard capsules (PL 42357/0286-0293) could be approved.

The products are indicated the following:

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. Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

These applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended, as generic medicines. The reference medicinal products are Lyrica hard capsules 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, and 300mg (EU/1/04/279/001-005,026,036; EU/1/04/279/006-010,037; EU/1/04/279/011-013,027,030,038,045; EU/1/04/279/014-016,039; EU/1/04/279/017-019,028,031,040; EU/1/04/279/ 020-022,041; EU/1/04/279/033-035,042; EU/1/04/279/023 – 025,029,032,043), which were granted Marketing Authorisations in the EU to Pfizer Limited on 8 July 2004.

No new non-clinical studies were conducted, which is acceptable given that the applications are based on being a generic medicinal products of a reference products that have been licensed for over 10 years.

With the exception of the bioequivalence study, no new clinical studies were conducted, which is acceptable given that the application is based on being a generic medicinal product of a reference product that has been in clinical use for over 10 years. The bioequivalence study was conducted in-line with current Good Clinical Practice (GCP).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place 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.

Marketing authorisations were granted for these products on 3 May 2019.

II QUALITY ASPECTS

II.1 Introduction

These products consist the active substance is pregabalin. Each hard capsule contains either 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg pregabalin.

In addition to pregabalin these products also contain the excipients:

Capsule content:
pregelatinized starch, mannitol, talc

Capsule shell:
25mg, 50mg: gelatin, titanium dioxide (E171)
75 mg, 100 mg, 300 mg: gelatin, titanium dioxide (E171), red iron oxide (E172)
200 mg, 225 mg: gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172)

Printing Ink:
Shellac, black iron oxide (E172), propylene glycol (E1520), ammonium hydroxide (E527)

The finished products are packaged in in a cardboard box containing the appropriate number of PVC /aluminium foil blisters as follows.

25 mg: 14, 56, or 84 hard capsules
50 mg: 7, 14, 56 or 84 hard capsules
75 mg:14, 56, or 84 hard capsules
100 mg: 7, 14, or 56, 84 hard capsules
150 mg: 14 or 56 hard capsules
200 mg:14, 56, or 84 hard capsules
225 mg:14 or 56 hard capsules
300 mg:14 or 56 hard capsules

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

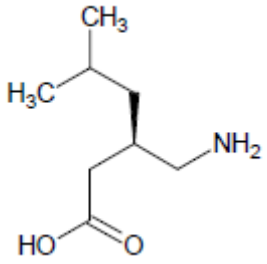
II.2 ACTIVE SUBSTANCE(S)

rINN: Pregabalin

Chemical Name: (3S)-3-(Aminomethyl)-5-methylhexanoic acid
(+) Isomer - (S)-(+)-3-Aminomethyl-5-methylhexanoic acid
(-) Isomer - (R)-(-)-3-Aminomethyl-5-methylhexanoic acid

Molecular Formula: $C_8H_{17}NO_2$

Chemical Structure:



Molecular Weight: 159.23
Appearance: White or almost white powder
Solubility: Sparingly soluble in water, very slightly soluble in methanol, practically insoluble in heptane.

Pregabalin is not the subject of a European Pharmacopoeia monograph.

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specification. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging complies with the current European regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3 DRUG PRODUCTS

Pharmaceutical development

A satisfactory account of the pharmaceutical development has been provided.

Comparative in vitro dissolution and impurity 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 gelatin, no excipients of animal or human origin are used in the final products. EDQM certificates have been provided for the excipient of animal origin.

This product does 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 formulae 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 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 3 years, without any 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 a 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 versions of an 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 a marketing authorisations is recommended.

IV CLINICAL ASPECTS

IV.1 Introduction

The clinical pharmacology, efficacy and safety of pregabalin are well-known. With the exception of data from a bioequivalence study, no new clinical data are provided or are required for this type of application. An overview based on a literature review and a review of the study is, thus, satisfactory.

IV. 2 Pharmacokinetics

In support of the application, the applicant submitted the following study:

An open label, balanced, randomized, two treatment, two period, two sequence, single oral dose, crossover bioequivalence study of Pregabalin 300 mg hard capsules vs the reference product: Lyrica® 300 mg Hard Capsules in normal, healthy, adult, human subjects under fasting conditions

After an overnight fast of at least 10 hours, a single oral dose (300 mg) of either the test or the reference product was administered to the subjects. Blood samples were taken pre-dose and up to 36 hours post dose, with a washout period of 8 days maintained between the treatment periods.

A summary of the pharmacokinetic results are presented below:

Parameters	Geometric Least Squares Means			90% Confidence Interval	Power (%)
	Test Product-T	Reference Product-R	Ratio (T / R)%		
$\ln C_{max}$	8841.187	8558.411	103.3	95.35 – 111.92	99.7
$\ln AUC_{0-t}$	71283.575	71338.758	99.9	97.26 – 102.65	100.0
$\ln AUC_{0-\infty}$	72858.791	72821.692	100.1	97.50 – 102.67	100.0

In line with the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**), the Test/Reference ratios and their 90% confidence intervals were within the specified limits to show bioequivalence between the test product and the reference product.

As the additional strengths of the product meet the biowaiver criteria specified in the current bioequivalence guideline, the results and conclusions from the bioequivalence study on the product strength can be extrapolated to the other strengths.

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

With the exception of the safety data submitted with the bioequivalence study, no new safety data were submitted with these applications.

The safety data from the bioequivalence study showed that the test and reference products were equally well tolerated. No new or unexpected safety issues were raised from the bioequivalence study.

IV.6 Risk Management Plan (RMP)

The Applicant has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC, 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 a marketing authorisations is recommended for these applications.

V USER CONSULTATION

A user consultation with target patient groups on the PIL has been performed on the basis of a bridging report making reference to the leaflet for Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg and 300mg Hard Capsules marketed by Pharmathen S.A. The bridging report submitted by the applicant is acceptable.

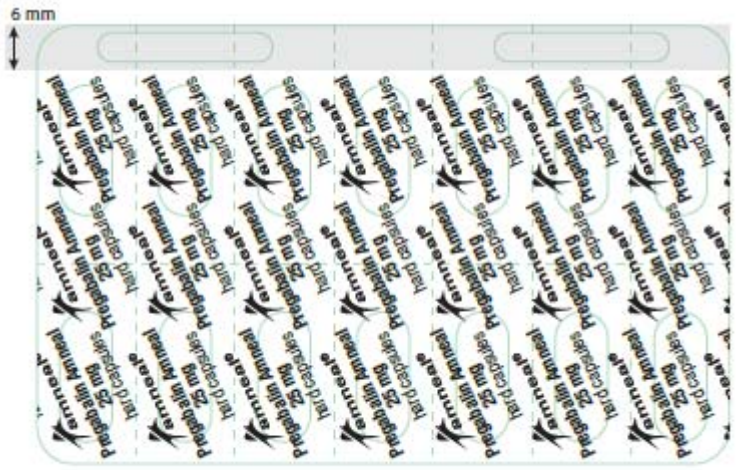
VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

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 product is bioequivalent to the reference product and, similarly, its benefit/risk is considered to be positive.

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

In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

Representative copies of the labels at the time of UK licensing are provided below.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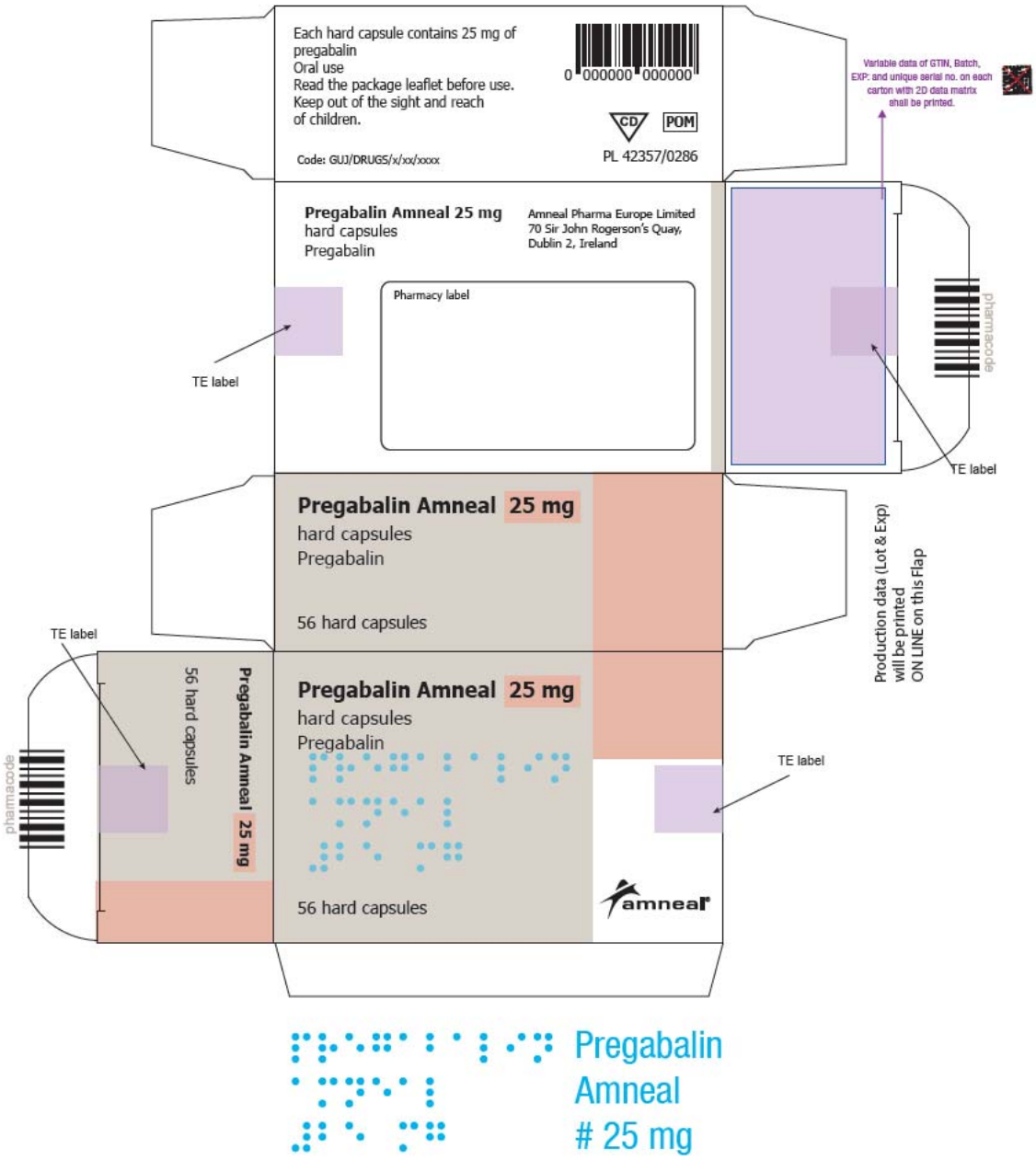
Each hard capsule contains 25 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
0 000000 000000
CD
POM
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0286
Variable data of GTIN, Batch, EXP: and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 25 mg
hard capsules
Pregabalin
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
Pharmacy label
TE label
pharmacode
TE label
Pregabalin Amneal 25 mg
hard capsules
Pregabalin
56 hard capsules
Production data (Lot & Exp) will be printed ON LINE on this Flap
TE label
pharmacode
56 hard capsules
Pregabalin Amneal 25 mg
Pregabalin Amneal 25 mg
hard capsules
Pregabalin
TE label
56 hard capsules
amneal
Pregabalin
Amneal
25 mg


6 mm
amneal
Pregabalin Amneal
50 mg
hard capsules


Each hard capsule contains 50 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0287
0 000000 000000
Variable data of GTIN, Batch, EXP: and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 50 mg
hard capsules
Pregabalin
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
Pharmacy label
CD
POM
Pregabalin Amneal 50 mg
hard capsules
Pregabalin
84 hard capsules
84 hard capsules
Pregabalin Amneal 50 mg
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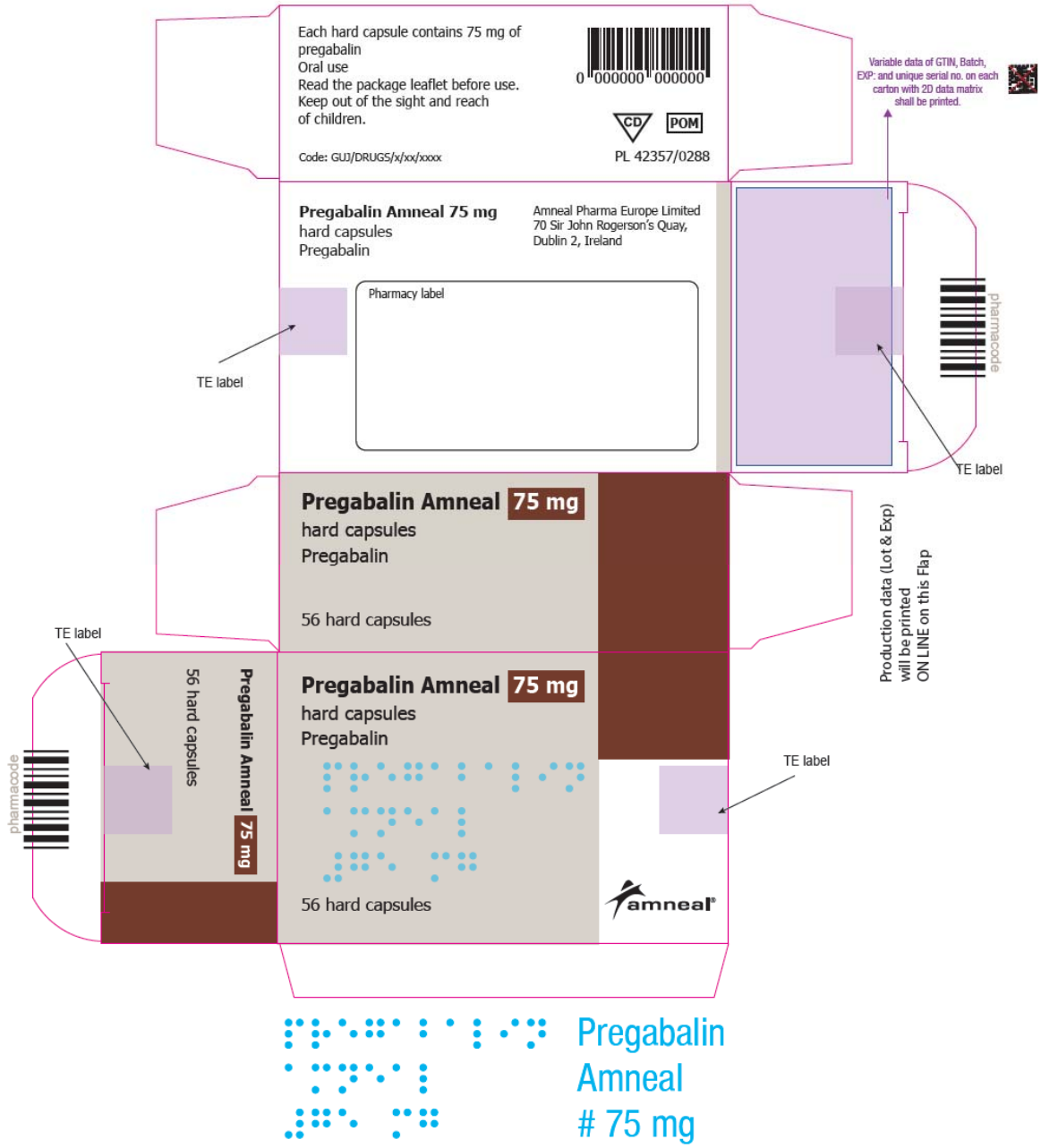
84 hard capsules
amneal
Pregabalin
Amneal
50 mg


6 mm


Each hard capsule contains 75 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
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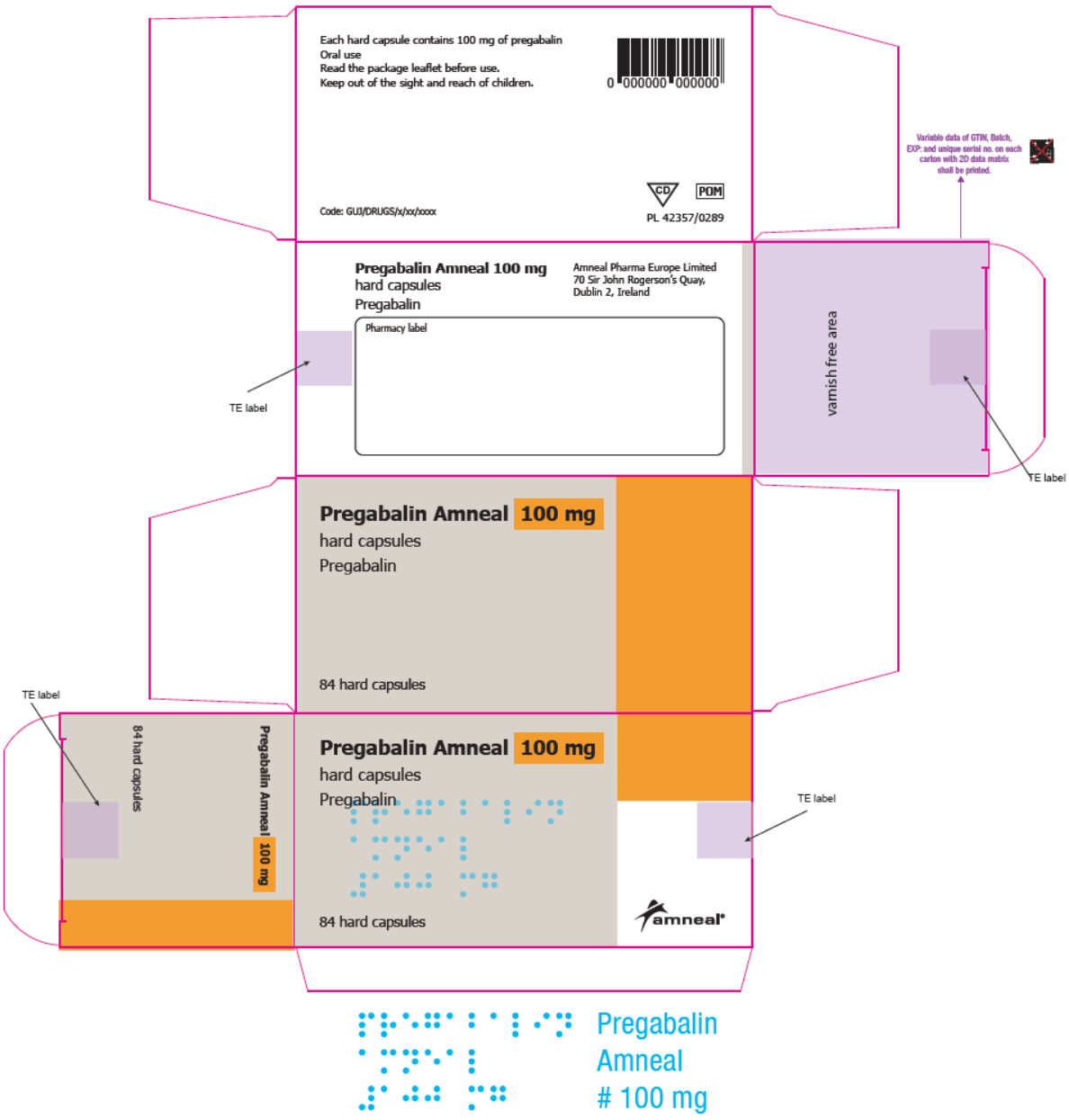
CD
POM
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0288
Variable data of GTIN, Batch, EXP: and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 75 mg
hard capsules
Pregabalin
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
Pharmacy label
TE label
pharmacode
TE label
Pregabalin Amneal 75 mg
hard capsules
Pregabalin
56 hard capsules
Production data (Lot & Exp) will be printed ON LINE on this Flap
TE label
pharmacode
56 hard capsules
Pregabalin Amneal 75 mg
Pregabalin Amneal 75 mg
hard capsules
Pregabalin
56 hard capsules
TE label
amneal
Pregabalin
Amneal
75 mg


58mm
6 mm
119mm
6 mm
amneal
Pregabalin Amneal
100 mg
hard capsules


Each hard capsule contains 100 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
0 000000 000000
Variable data of GTIN, Batch, EXP: and unique serial no. on each carton with 2D data matrix shall be printed.
Code: GUI/DRUGS/x/xx/xxxx
CD
POM
PL 42357/0289
Pregabalin Amneal 100 mg
hard capsules
Pregabalin
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
Pharmacy label
TE label
varnish free area
TE label
Pregabalin Amneal 100 mg
hard capsules
Pregabalin
84 hard capsules
TE label
84 hard capsules
Pregabalin Amneal 100 mg
Pregabalin Amneal 100 mg
hard capsules
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Pregabalin
Amneal
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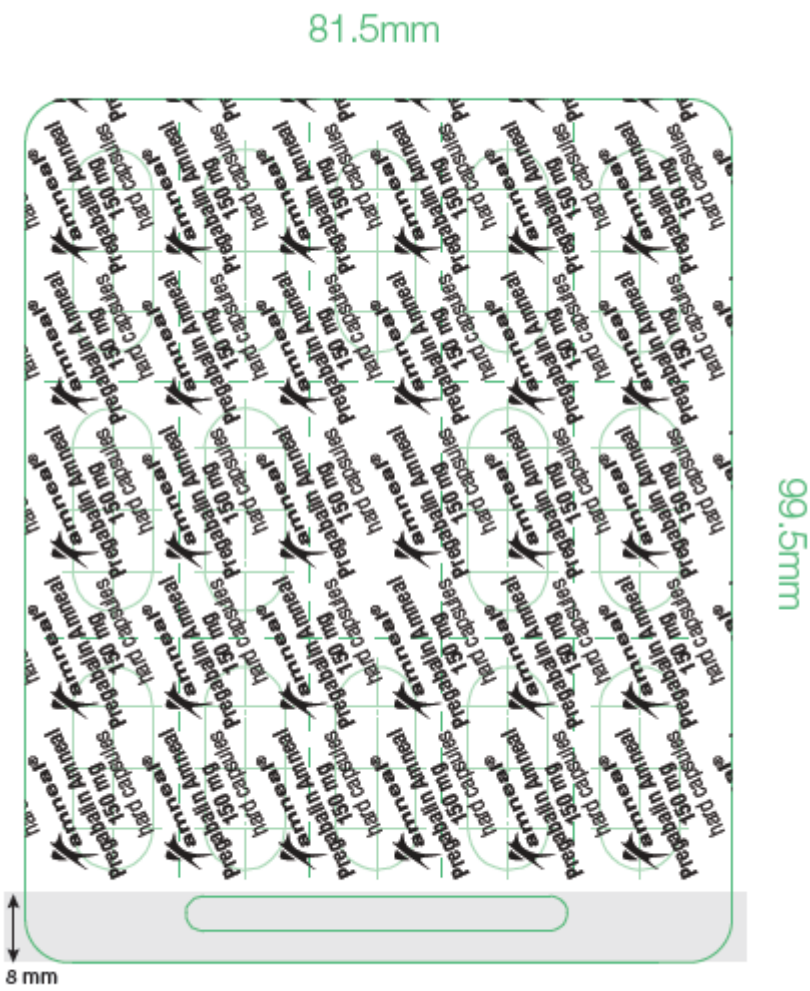
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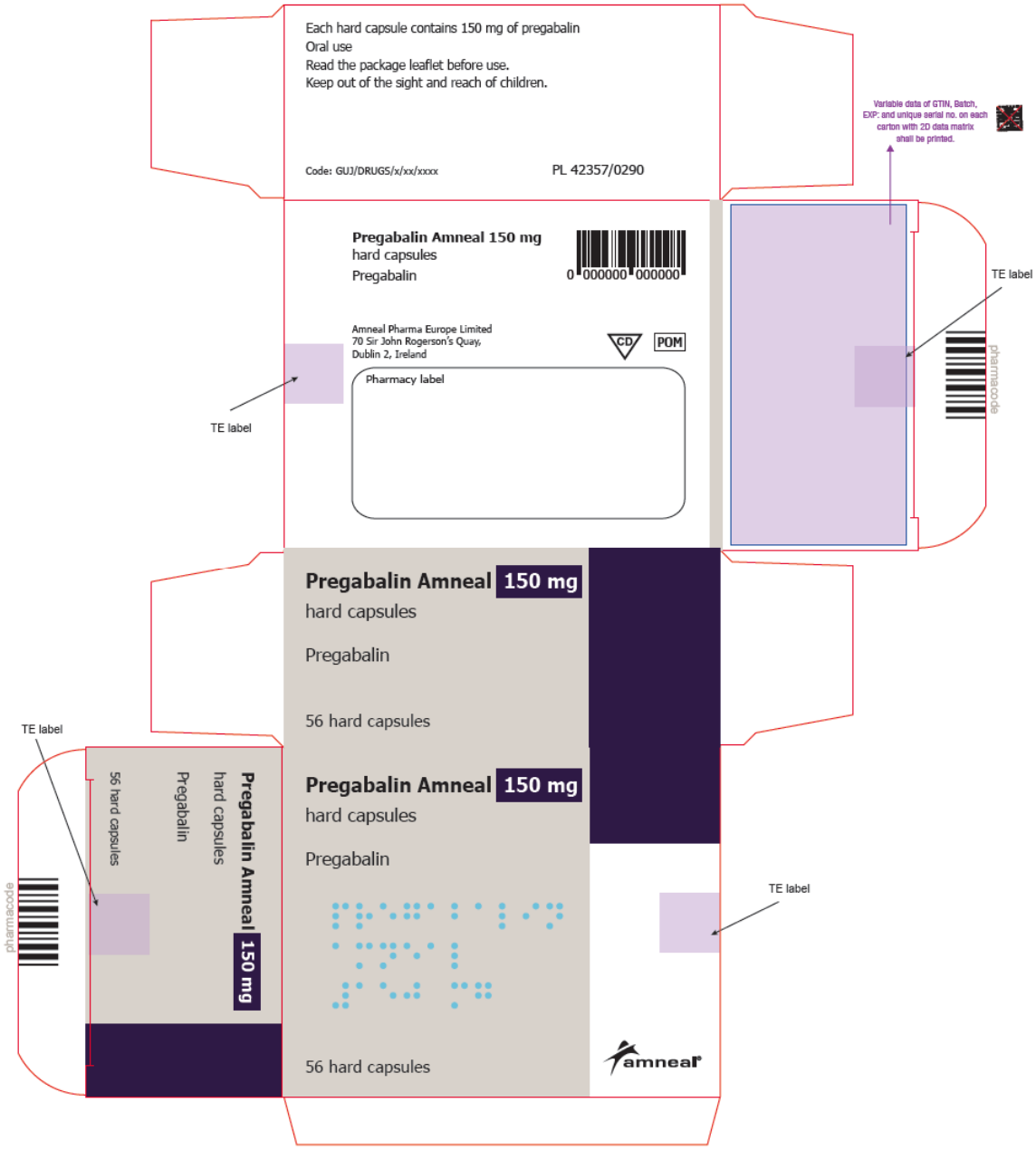
Each hard capsule contains 150 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0290
Variable data of GTIN, Batch, EXP, and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 150 mg
hard capsules
Pregabalin
0 000000 000000
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
CD
POM
Pharmacy label
TE label
TE label
pharmacode
Pregabalin Amneal 150 mg
hard capsules
Pregabalin
56 hard capsules
Pregabalin Amneal 150 mg
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hard capsules
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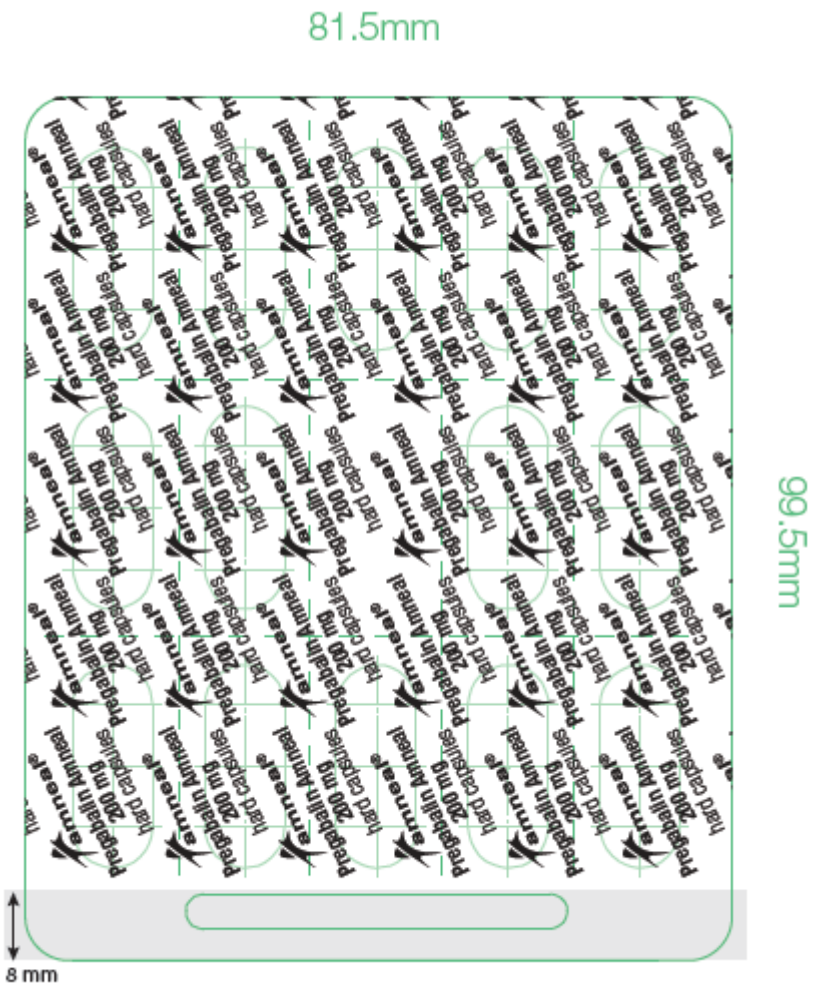
TE label
amneal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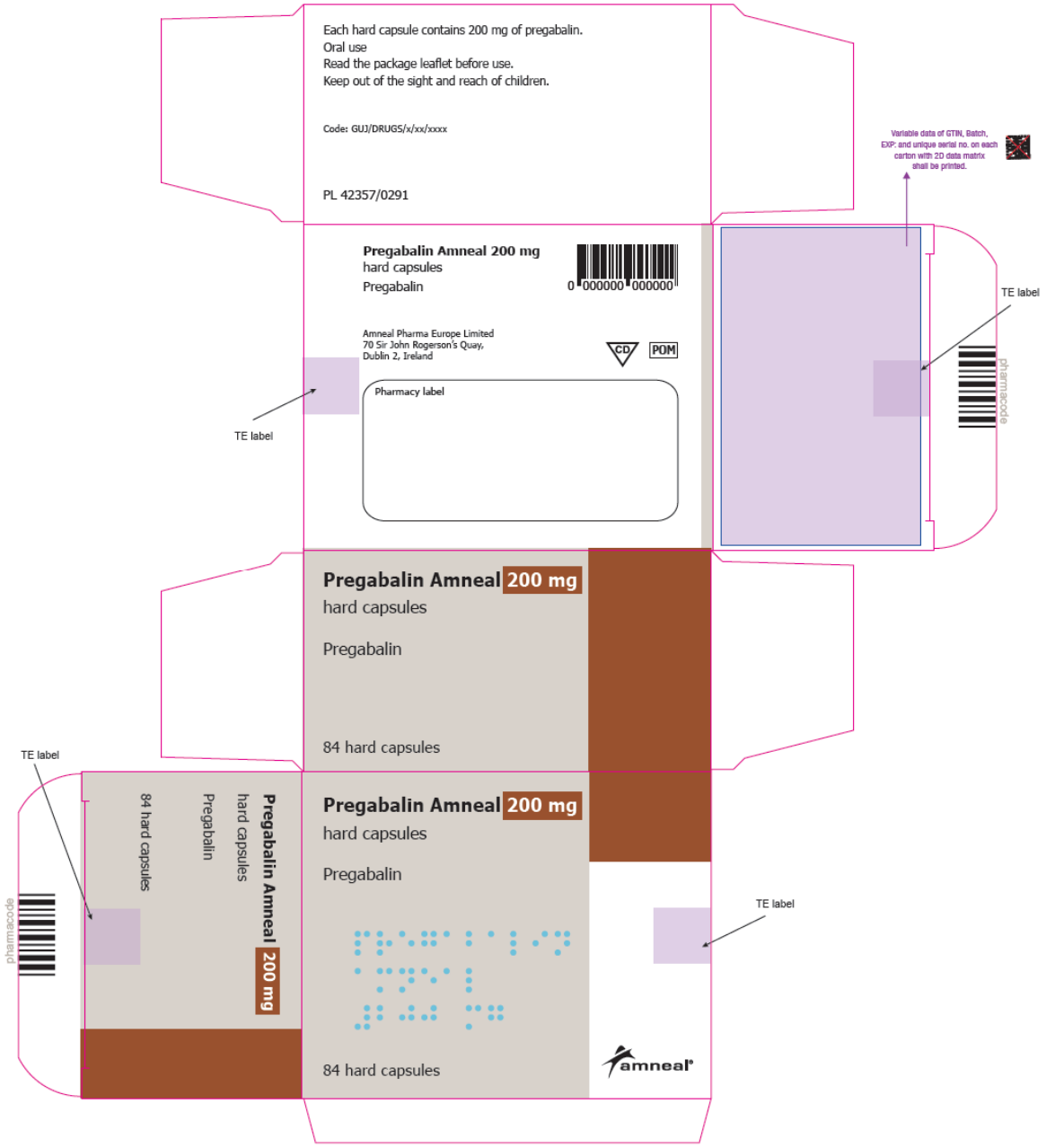
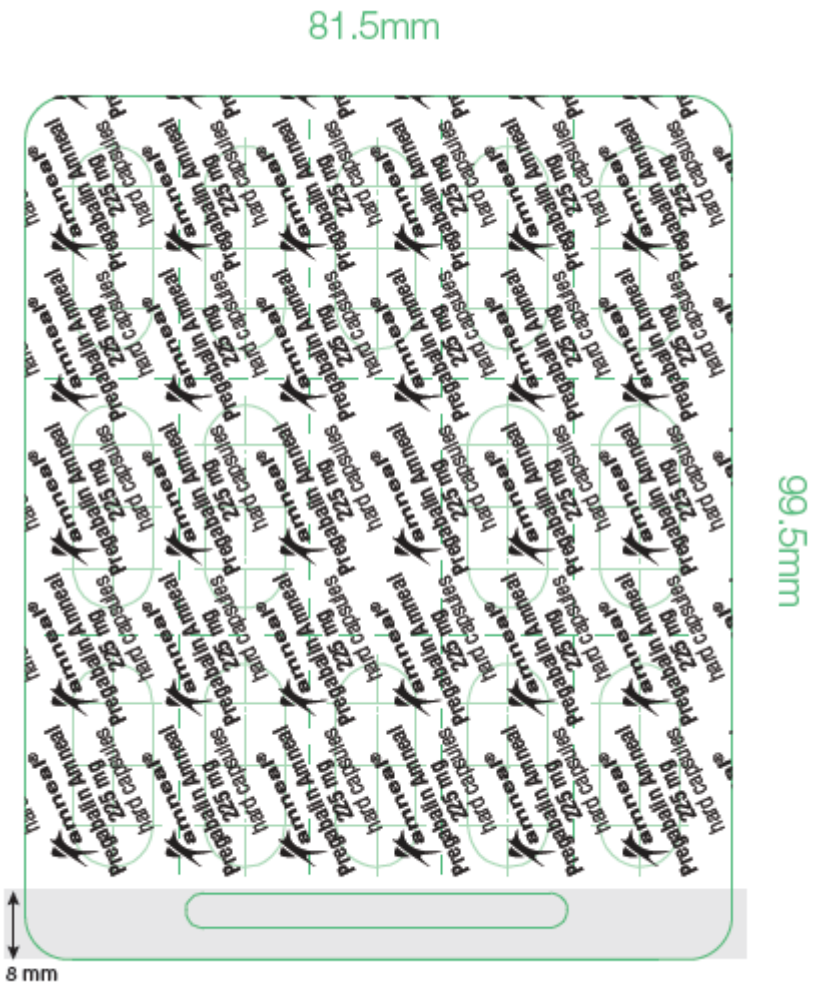
99.5mm
8 mm


Each hard capsule contains 200 mg of pregabalin.
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0291
Variable data of GTIN, Batch, EXP: and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 200 mg
hard capsules
Pregabalin
0 000000 000000
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
CD
POM
Pharmacy label
TE label
TE label
pharmacode
Pregabalin Amneal 200 mg
hard capsules
Pregabalin
84 hard capsules
TE label
pharmacode
84 hard capsules
Pregabalin
hard capsules
Pregabalin Amneal 200 mg
Pregabalin Amneal 200 mg
hard capsules
Pregabalin
84 hard capsules
TE label
amneal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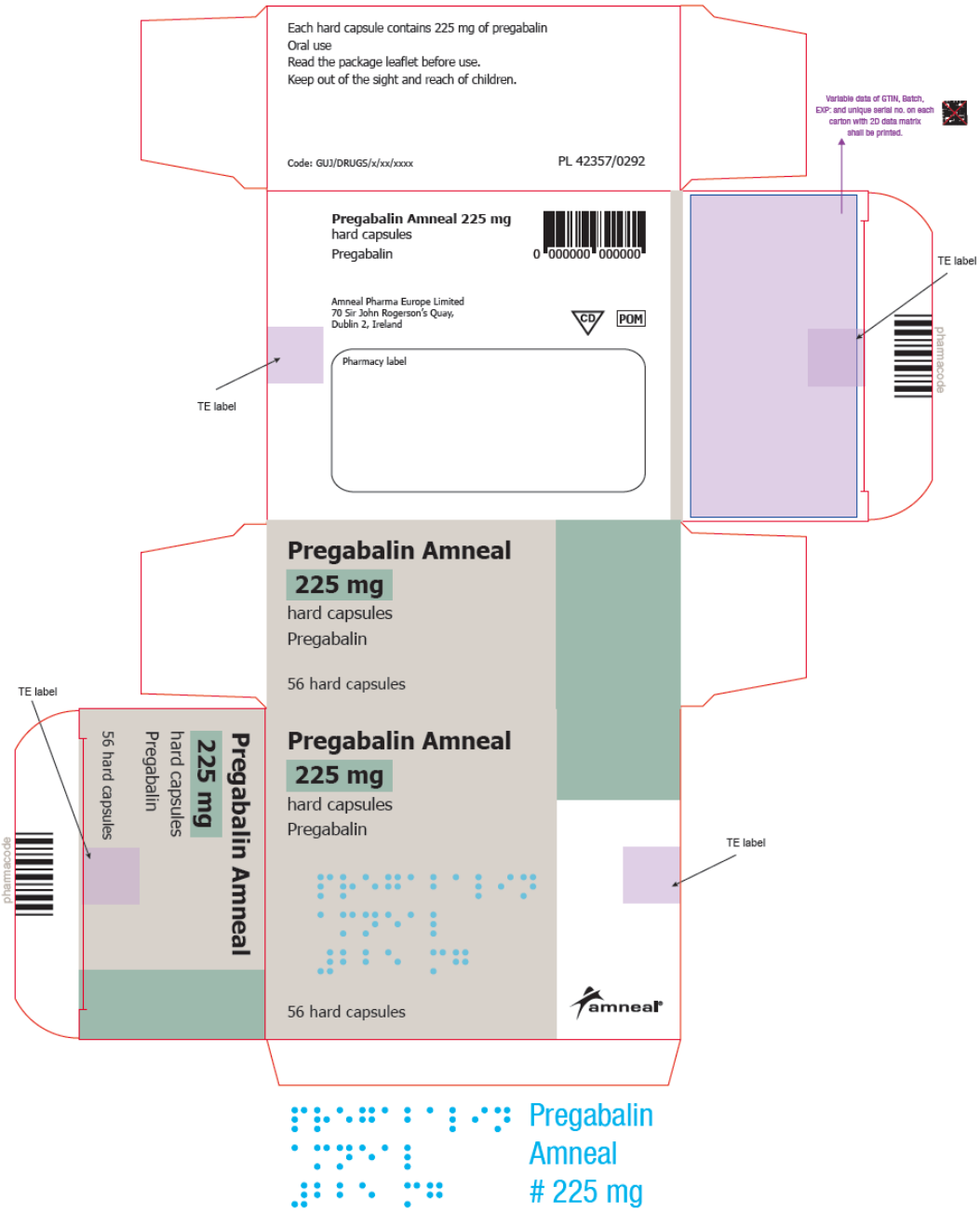
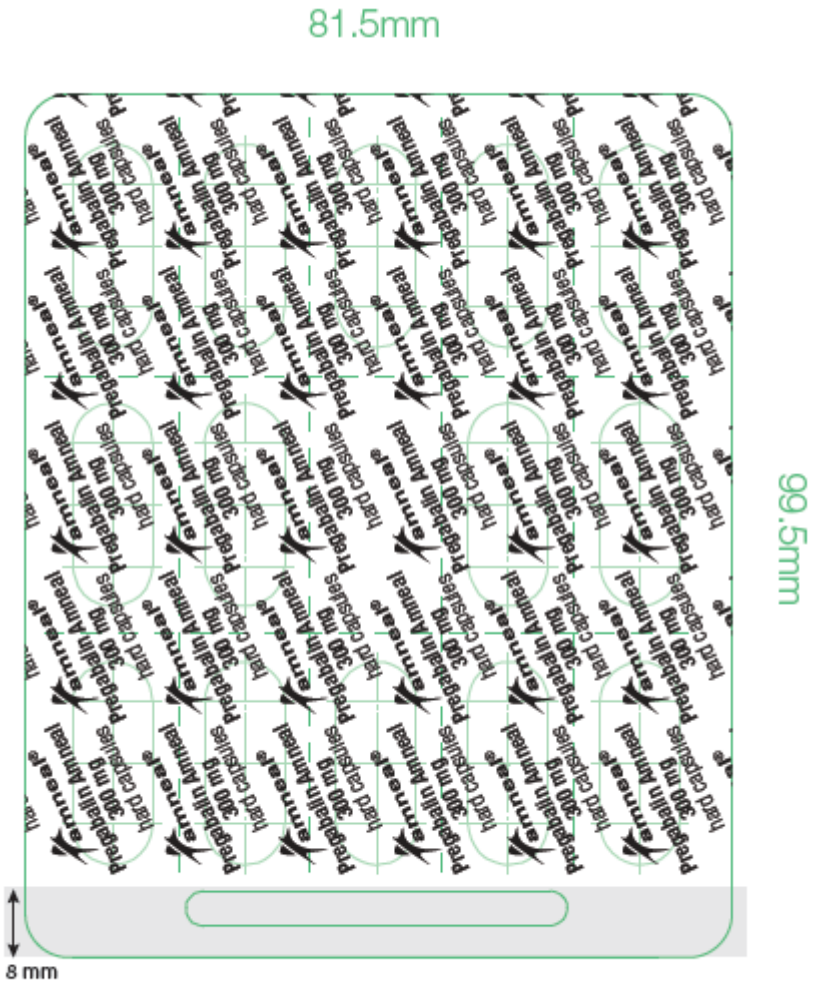
99.5mm
8 mm


Each hard capsule contains 225 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0292
Variable data of GTIN, Batch, EXP. and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 225 mg
hard capsules
Pregabalin
0 000000 000000
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
CD
POM
Pharmacy label
TE label
TE label
pharmacode
Pregabalin Amneal
225 mg
hard capsules
Pregabalin
56 hard capsules
Pregabalin Amneal
225 mg
hard capsules
Pregabalin
56 hard capsules
TE label
TE label
pharmacode
Pregabalin Amneal 225 mg
hard capsules
Pregabalin
56 hard capsules
amneal
Pregabalin
Amneal
225 mg


81.5mm
99.5mm
8 mm


Each hard capsule contains 300 mg of pregabalin
Oral use
Read the package leaflet before use.
Keep out of the sight and reach of children.
Code: GUJ/DRUGS/x/xx/xxxx
PL 42357/0293
Variable data of GTIN, Batch, EXP. and unique serial no. on each carton with 2D data matrix shall be printed.
Pregabalin Amneal 300 mg
hard capsules
Pregabalin
0 000000 000000
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay,
Dublin 2, Ireland
CD
POM
Pharmacy label
TE label
TE label
pharmacode
Pregabalin Amneal 300 mg
hard capsules
Pregabalin
56 hard capsules
TE label
Pregabalin Amneal 300 mg
hard capsules
Pregabalin
56 hard capsules
TE label
pharmacode
Pregabalin Amneal 300 mg
hard capsules
Pregabalin
56 hard capsules
amneal
Pregabalin
Amneal
300 mg

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 product licence are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of start of the procedure**	**Date of end of procedure**	**Outcome**	**Assessment report attached Y/N**