Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Lercanidipine hydrochloride 10 mg film-coated tablets
Lercanidipine hydrochloride 20 mg film-coated tablets

lercanidipine hydrochloride hemihydrate

PL 49445/0168-0169

Amarox Limited

LAY SUMMARY

Lercanidipine hydrochloride 10 mg film-coated tablets
Lercanidipine hydrochloride 20 mg film-coated tablets
lercanidipine hydrochloride hemihydrate

This is a summary of the Public Assessment Report (PAR) for Lercanidipine hydrochloride 10 mg and 20 mg film-coated tablets. 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 Lercanidipine hydrochloride tablets in this lay summary for ease of reading.

For practical information about using Lercanidipine hydrochloride tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Lercanidipine hydrochloride tablets 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, called Zanidip 10 mg and 20 mg film-coated tablets.

Lercanidipine hydrochloride is used to treat high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old).

How do Lercanidipine hydrochloride tablets work?
These medicines contain the active ingredient lercanidipine hydrochloride hemihydrate, which belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives) that lower blood pressure.

How are Lercanidipine hydrochloride tablets used?
The pharmaceutical form of these medicines is a film-coated tablet and the route of administration is oral (by mouth).

In adults, the recommended dose is 10 mg once daily at the same time each day, preferably in the morning at least 15 minutes before breakfast. A doctor may advise the patient to increase the dose to one Lercanidipine hydrochloride 20 mg tablet daily, if needed.

The score line on the tablets is only to facilitate breaking for ease of swallowing and not to divide into equal doses. The tablets should preferably be swallowed whole with some water.

These medicines should not be used in children under 18 years of age.

No adjustment of the daily dose is required for elderly patients; however, special care should be exercised in starting treatment.

In patients with liver or kidney problems, special care is needed in starting treatment and an increase in daily dose to 20 mg should be approached with caution.

For further information on how Lercanidipine hydrochloride tablets 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 Lercanidipine hydrochloride tablets have been shown in studies?
Because Lercanidipine hydrochloride tablets 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 Lercanidipine hydrochloride tablets?
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 medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Lercanidipine hydrochloride tablets are generic medicines and are bioequivalent to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

Why were Lercanidipine hydrochloride tablets approved?
It was concluded that, Lercanidipine hydrochloride tablets 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 they can be approved for use.

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

There are no safety concerns associated with use of Lercanidipine hydrochloride tablets.

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 Lercanidipine hydrochloride tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Lercanidipine hydrochloride tablets

Marketing authorisations for Lercanidipine hydrochloride tablets were granted in the United Kingdom on 23 June 2022.

The full PAR for Lercanidipine hydrochloride tablets follows this summary.

This summary was last updated in August 2022.

TABLE OF 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 Lercanidipine hydrochloride 10 mg and 20 mg film-coated tablets (PL 49445/0168-0169) could be approved.

The products are approved for the following indication:
In adults for the treatment of mild to moderate essential hypertension.

Lercanidipine is a calcium antagonist of the dihydropyridine group and inhibits the transmembrane influx of calcium into cardiac and smooth muscle. The mechanism of its antihypertensive action is due to a direct relaxant effect on vascular smooth muscle thus lowering total peripheral resistance.

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, Zanidip 10 mg and 20 mg film-coated tablets, that have been licensed 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.

With the exception of the bioequivalence study, no new clinical studies were conducted, which is acceptable given that the applications are for generic medicinal products of suitable reference products. 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 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.

Marketing authorisations for Lercanidipine hydrochloride tablets were granted in the United Kingdom on 23 June 2022.

II QUALITY ASPECTS

II.1 Introduction

These products consist of film-coated tablets.

Each film-coated tablet contains 10 mg lercanidipine hydrochloride (equivalent to 10.139 mg lercanidipine hydrochloride hemihydrate). Each 20 mg film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).

In addition to lercanidipine hydrochloride hemihydrate, these products also contain the following excipients:

Tablet core:
Lactose monohydrate
Cellulose, microcrystalline
Sodium starch glycolate
Povidone
Magnesium stearate

Tablet coat:
Polyvinyl alcohol-part. Hydrolyzed (E1203)
Titanium dioxide (E171)
Macrogol (E1521)
Talc (E553b)
Iron oxide yellow (E172)
Iron oxide red (E172)

The finished products are packaged in white opaque polyvinyl chloride/Aclar-Aluminium foil and OPA/Alu foil/PE coex coating with polyethylene, desiccant, polyethylene coex – Aluminium foil in a pack size of 28, 30, 50 and 100 tablets. 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: Lercanidipine hydrochloride

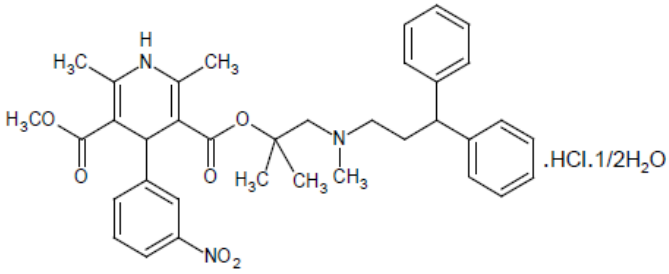
Chemical Name: 1,4-Dihydro-2,6-dimethyl-4-(3-nitrophenyl)-3,5 Pyridine dicarboxylic acid 2-[(3,3-diphenylpropyl) methyl amino]-1,1- Dimethyl ethyl methyl ester Hydrochloride.

Methyl 1,1, N-trimethyl-N-(3,3-diphenylpropyl)-2-amino ethyl 1,4-dihydro2,6-dimethyl-4-(3-nitrophenyl) pyridine-3,5-dicarboxylate Hydrochloride.

Methyl 1,1-dimethyl-2-[N-(3,3-diphenylpropyl)-N-methyl amino] ethyl 2,6-dimethyl-4-(3-nitrophenyl)-1,4-dihydro pyridine-3,5-dicarboxylate Hydrochloride

Molecular Formula: $C_{36}H_{41}N_3O_6.HCl.1/2H_2O$

Chemical Structure:



Molecular Weight: 657.21
Appearance: A light yellow to yellow amorphous powder
Solubility: Soluble in dimethylformamide, dichloromethane and in methanol

Lercanidipine hydrochloride hemihydrate 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 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 lactose monohydrate, 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.

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 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 lercanidipine hydrochloride hemihydrate 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 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 lercanidipine hydrochloride hemihydrate are well-known. With the exception of data from one 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 this study is, thus, satisfactory.

IV. 2 Pharmacokinetics

In support of the application, the applicant submitted the following bioequivalence study.

Bioequivalence study

This study was an open label, randomised, single-dose, 4-period, replicate crossover bioequivalence study comparing the test product Lercanidipine hydrochloride 20 mg film coated tablets versus the reference product Zanidip 20mg film-coated tablets in healthy, adult, human subjects under fasting conditions.

After an overnight fasting of at least 10 hours, a single oral dose of either test product or reference product was administered with 240 mL of drinking water at room temperature with the subjects in sitting posture. The tablets were swallowed whole without chewing or crushing. Blood samples were taken pre-dose and up to 48 hours post dose, with a washout period of 7 days between the treatment periods.

A summary of the pharmacokinetic results are presented below:

R-lercanidipine

AUC_{0-t}:

Parameters	Geometric Least Squares Means			90% Confidence Interval	S_{wr}	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R) %				
AUC_{0-t} (hr*pg/mL)	30138.909	30842.465	97.72	90.92 - 105.03	0.276	28.2	99.97

Parameters	Geometric Least Squares Means			90% Confidence Interval	Widen Acceptance Limits %	S_{wr}	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R) %					
C_{max} (pg/mL)	7138.485	6568.271	108.68	99.58 - 118.61	76.12 - 131.37	0.359	37.1	99.44

S-lercanidipine

Parameters	Geometric Least Squares Means			90% Confidence Interval	S_{wr}	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R) %				
AUC_{0-t} (hr*pg/mL)	31297.193	31875.315	98.19	91.86 - 104.95	0.259	26.3	99.99

Parameters	Geometric Least Squares Means			90% Confidence Interval	Widen Acceptance Limits %	S_{wr}	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R) %					
C_{max} (pg/mL)	8162.492	7509.350	108.70	99.82 - 118.37	76.12 - 131.37	0.359	37.1	99.59

In accordance with the regulatory requirements, 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 strength (10 mg) of the product meet the biowaiver criteria specified in the current bioequivalence guideline, the results and conclusions from the bioequivalence study on the 20mg product strength can be extrapolated to the other strength.

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 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 Levetiracetam Hetero 750 mg Film-Coated Tablets (Hetero Europe S.L) for design and layout, and Lercanidipine Hydrochloride 10 mg and 20 mg film-coated tablets (Arrow Generics Limited) for content. The bridging report submitted by the applicant is acceptable.

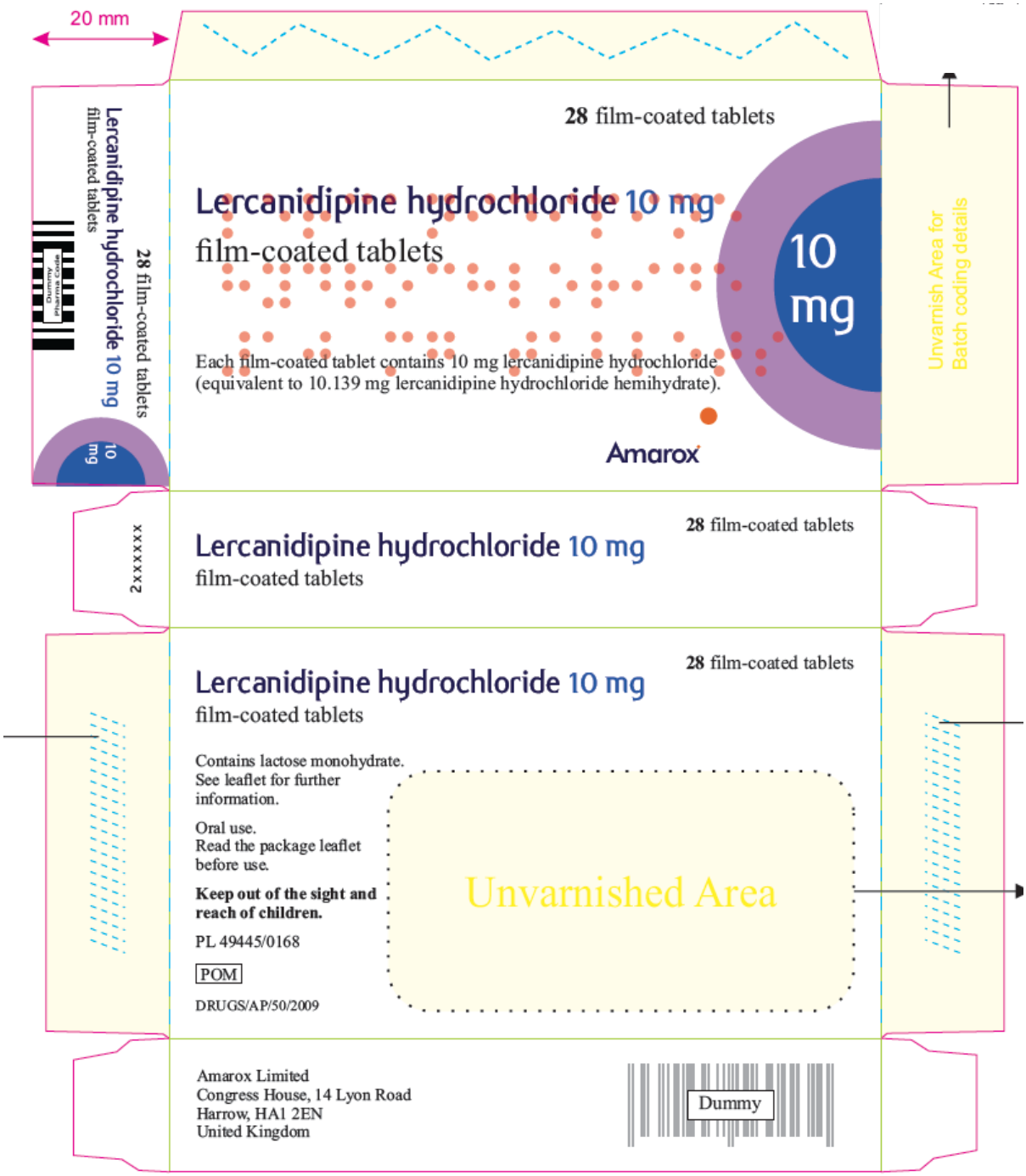
VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with lercanidipine hydrochloride hemihydrate 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 PILs for these products are available on the MHRA website.

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


20 mm
Lercanidipine hydrochloride 10 mg
film-coated tablets
28 film-coated tablets
10 mg
28 film-coated tablets
Lercanidipine hydrochloride 10 mg
film-coated tablets
Each film-coated tablet contains 10 mg lercanidipine hydrochloride (equivalent to 10.139 mg lercanidipine hydrochloride hemihydrate).
Amarox
10 mg
Unvarnish Area for Batch coding details
xxxxxx2
28 film-coated tablets
Lercanidipine hydrochloride 10 mg
film-coated tablets
28 film-coated tablets
Lercanidipine hydrochloride 10 mg
film-coated tablets
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.
PL 49445/0168
POM
DRUGS/AP/50/2009
Unvarnished Area
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
Dummy


22 mm
30 film-coated tablets
Lercanidipine hydrochloride 10 mg film-coated tablets
10 mg
30 film-coated tablets
Lercanidipine hydrochloride 10 mg
film-coated tablets
Each film-coated tablet contains 10 mg lercanidipine hydrochloride (equivalent to 10.139 mg lercanidipine hydrochloride hemihydrate).
Amarox
10 mg
2xxxxxx
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30 film-coated tablets
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film-coated tablets
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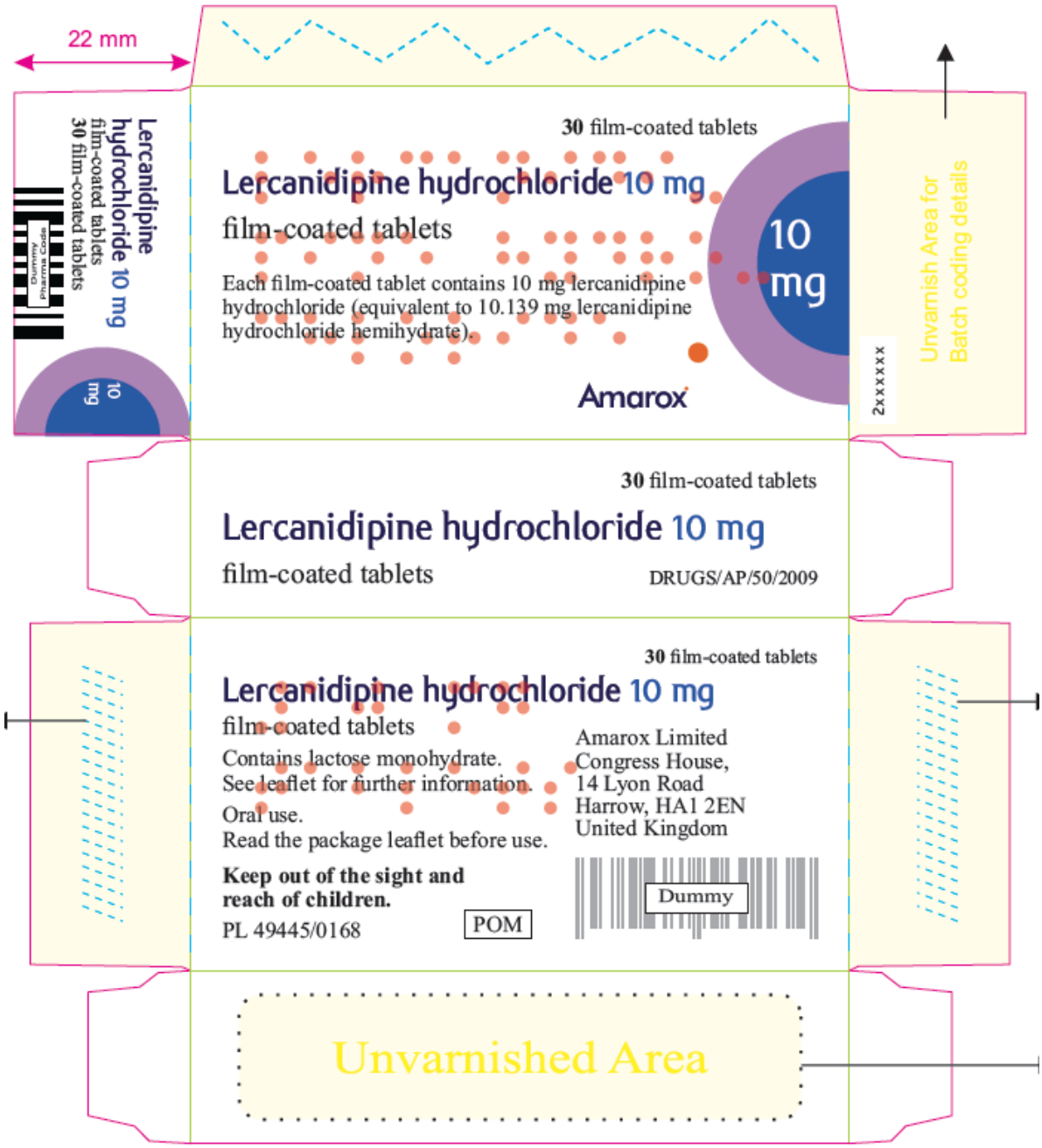
United Kingdom
Dummy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30 mm
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Unvarnished Area
Provision for anti tampering
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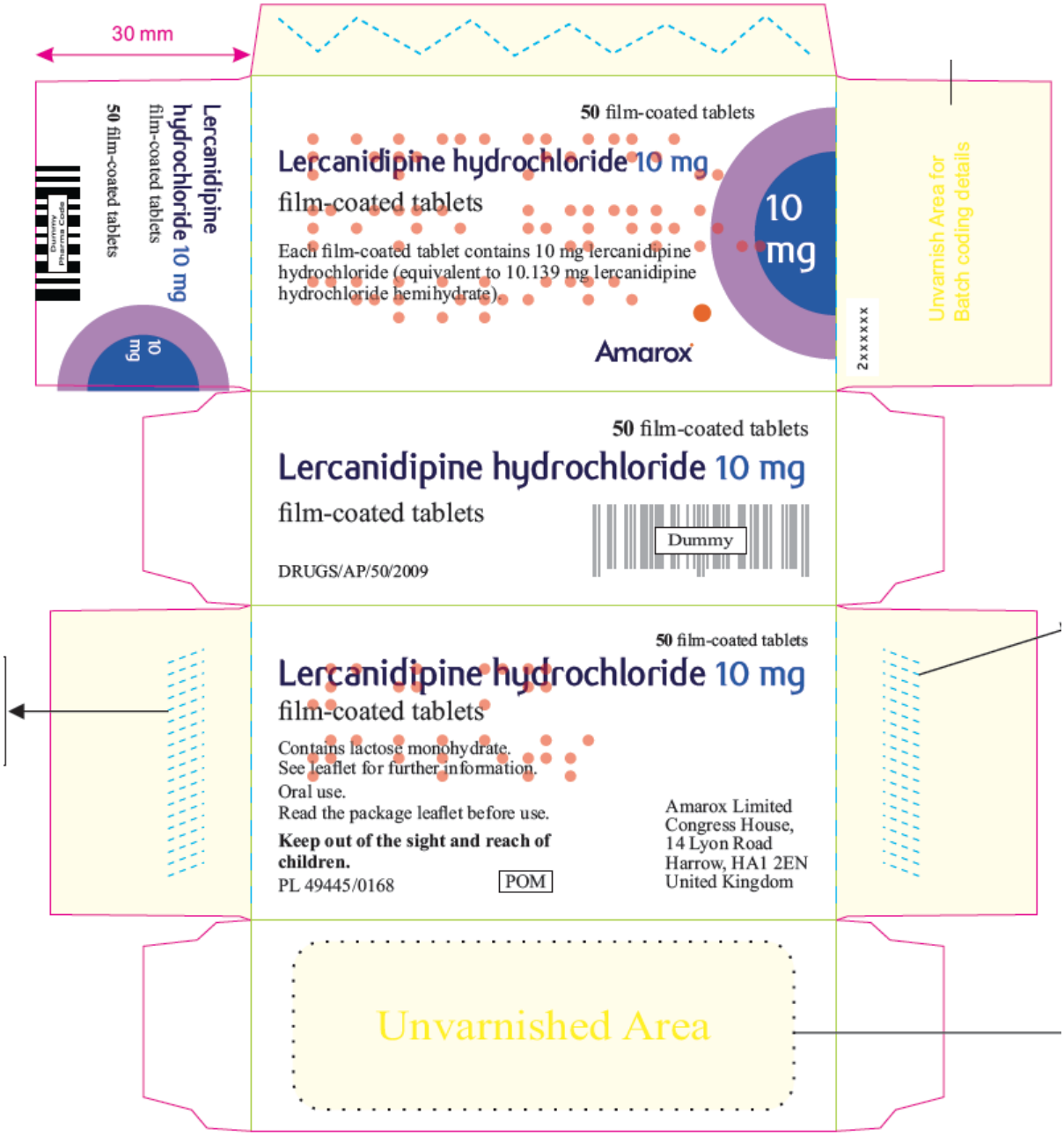
United Kingdom
Dummy
DRUGS/AP/50/2009


30 mm
50 film-coated tablets
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50 mm
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Dummy
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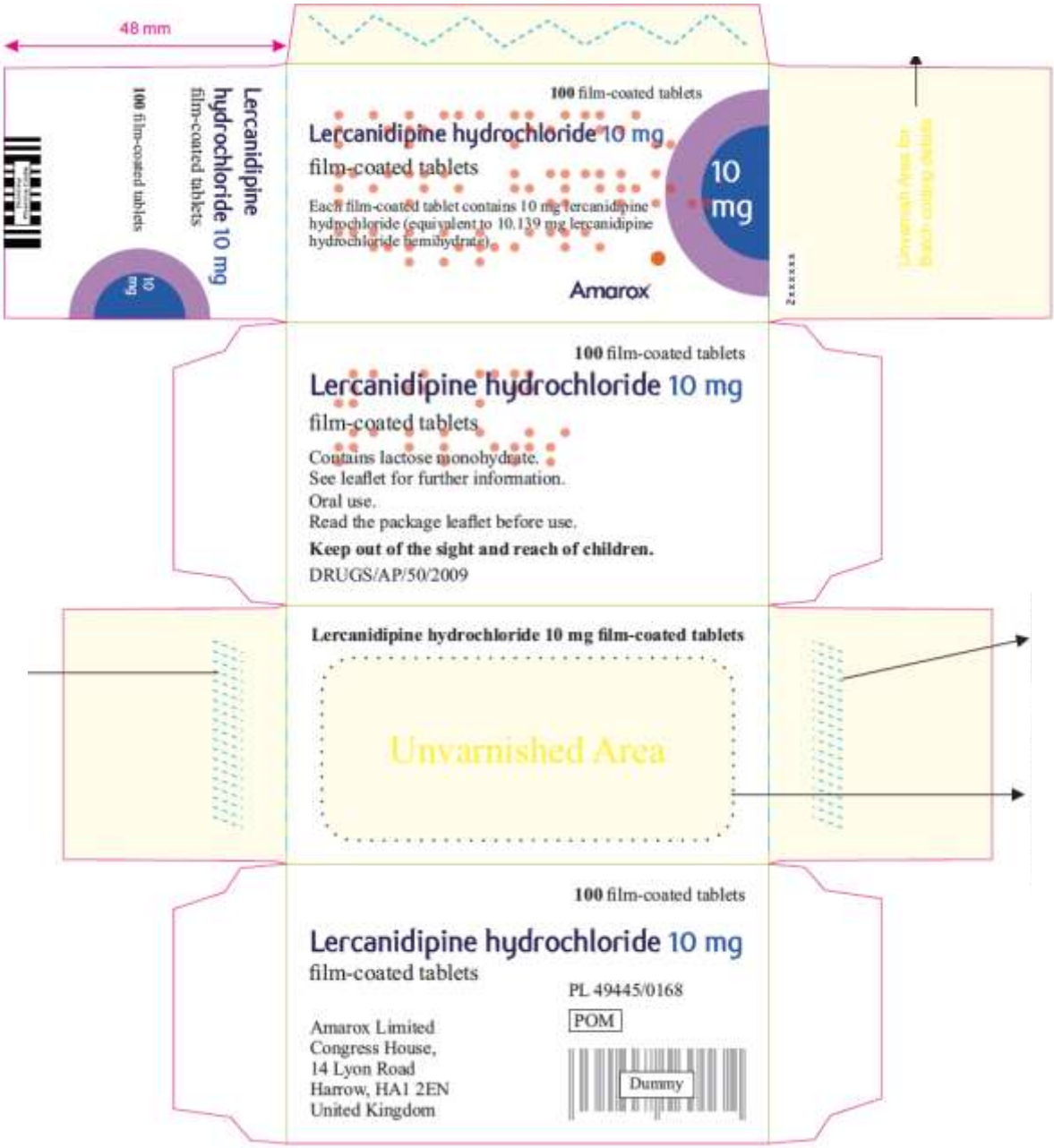
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Lercanidipine hydrochloride 10 mg
film-coated tablets
100 film-coated tablets
10 mg
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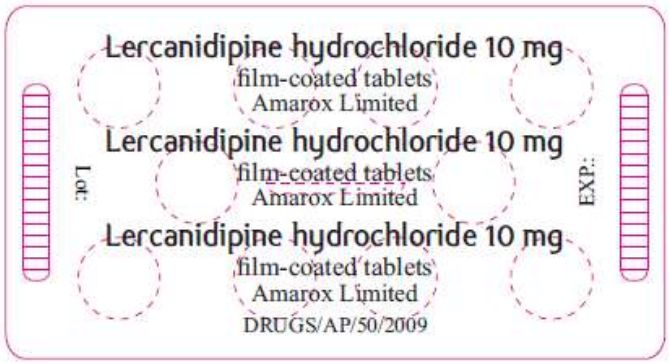
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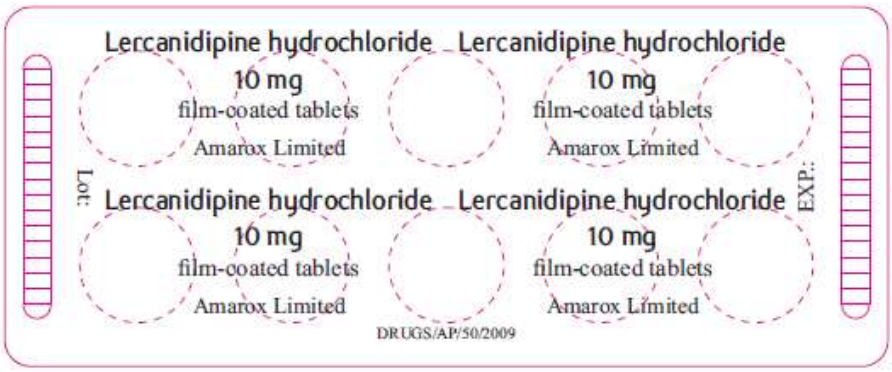
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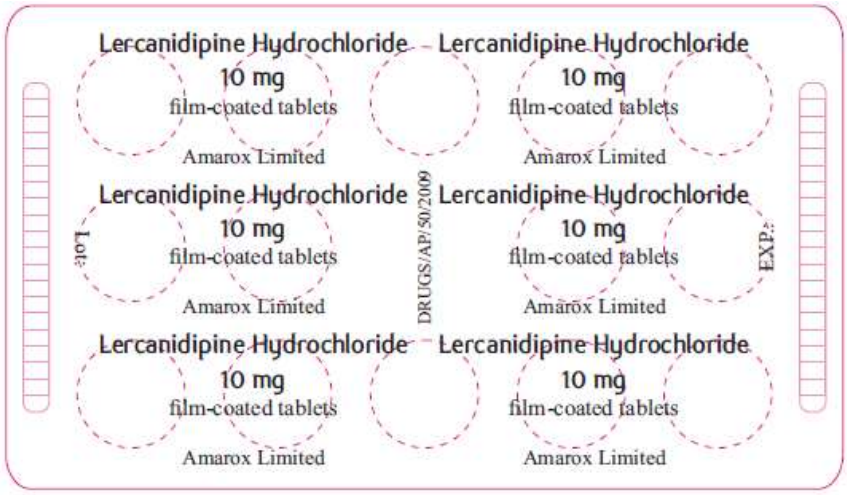
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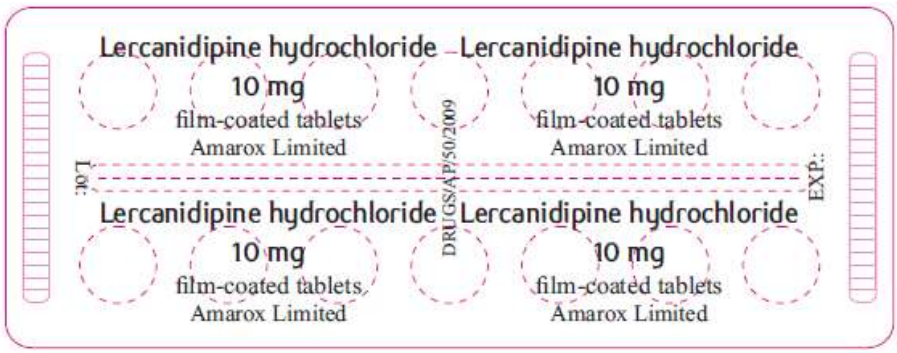
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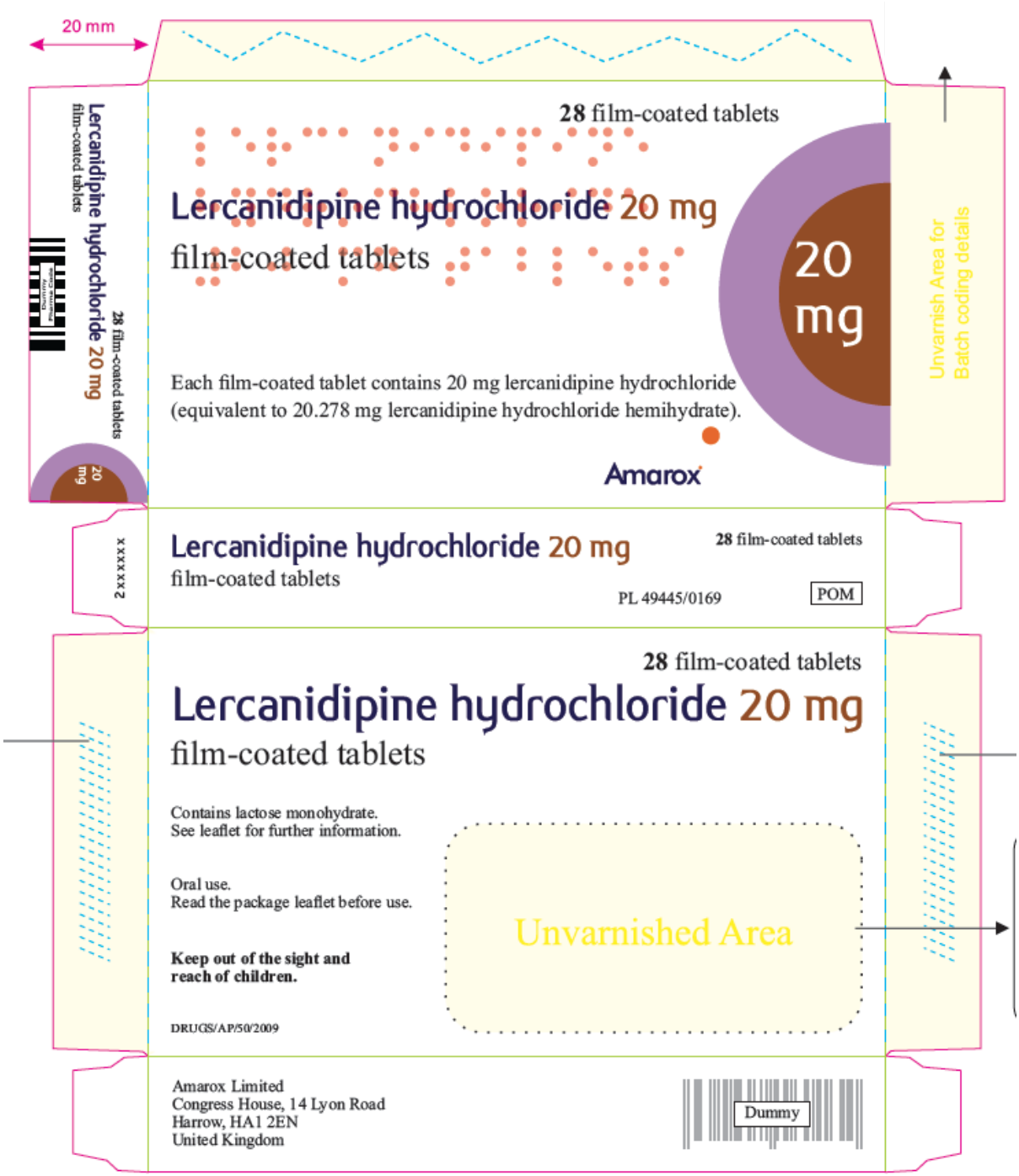
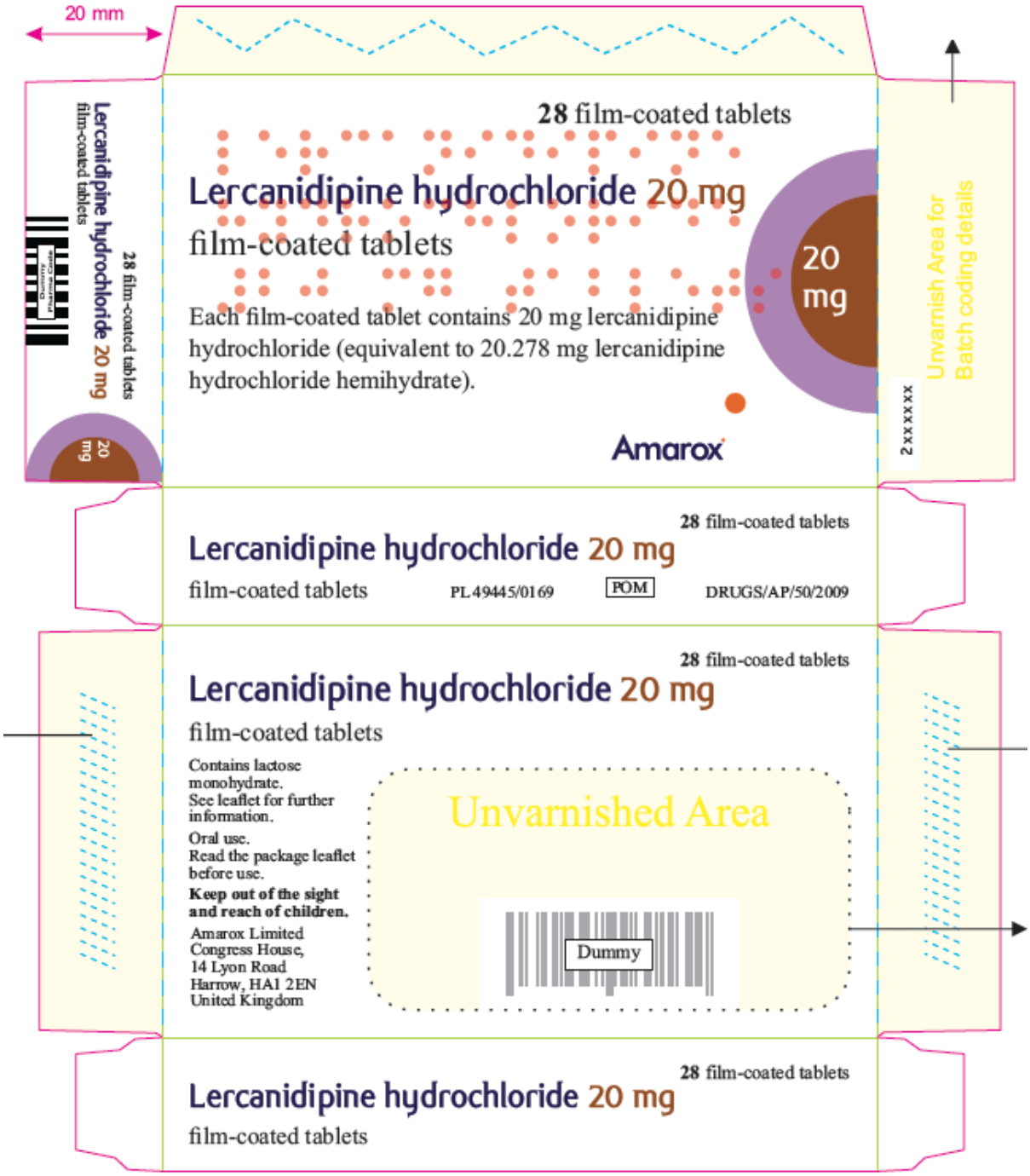
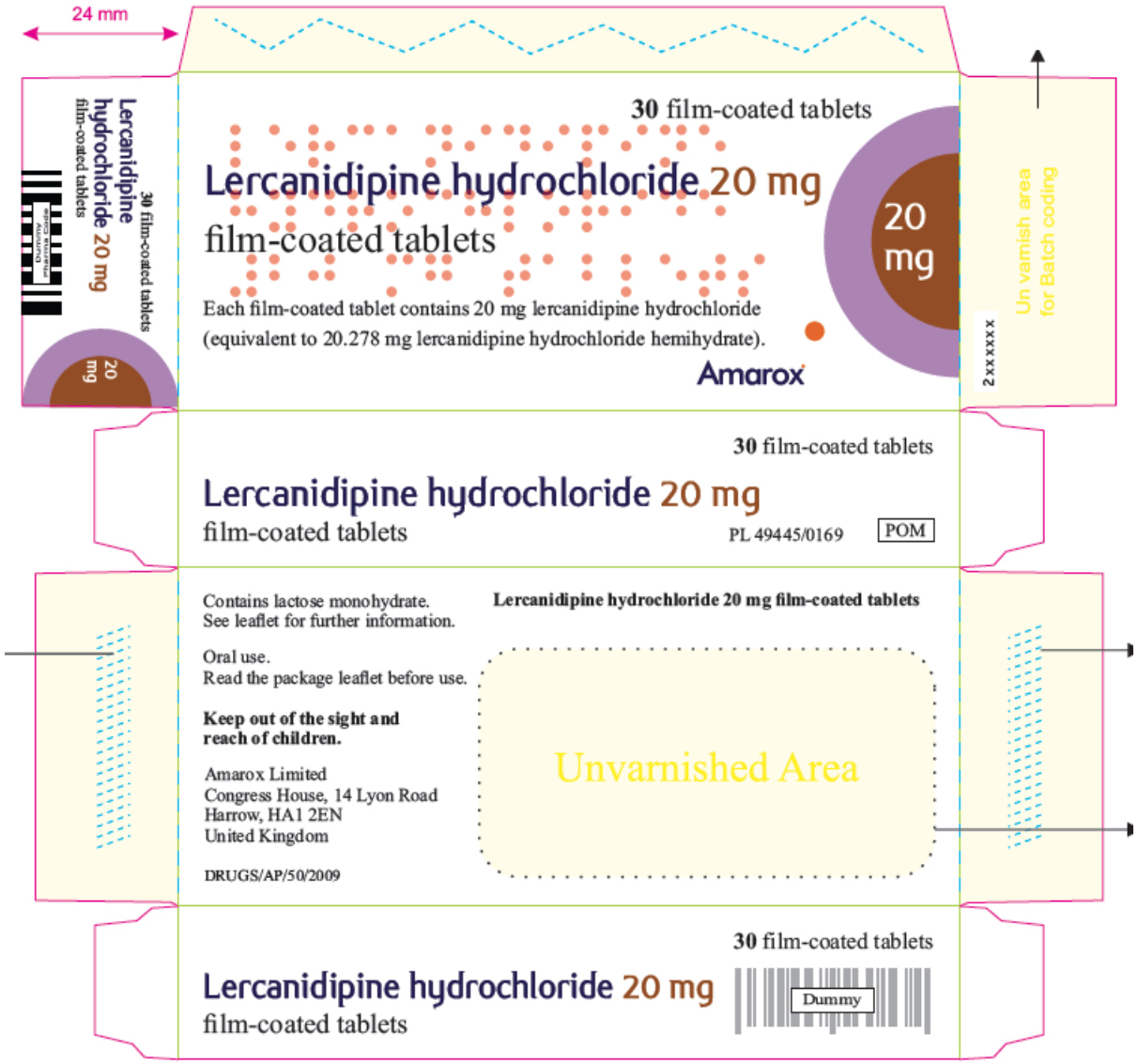
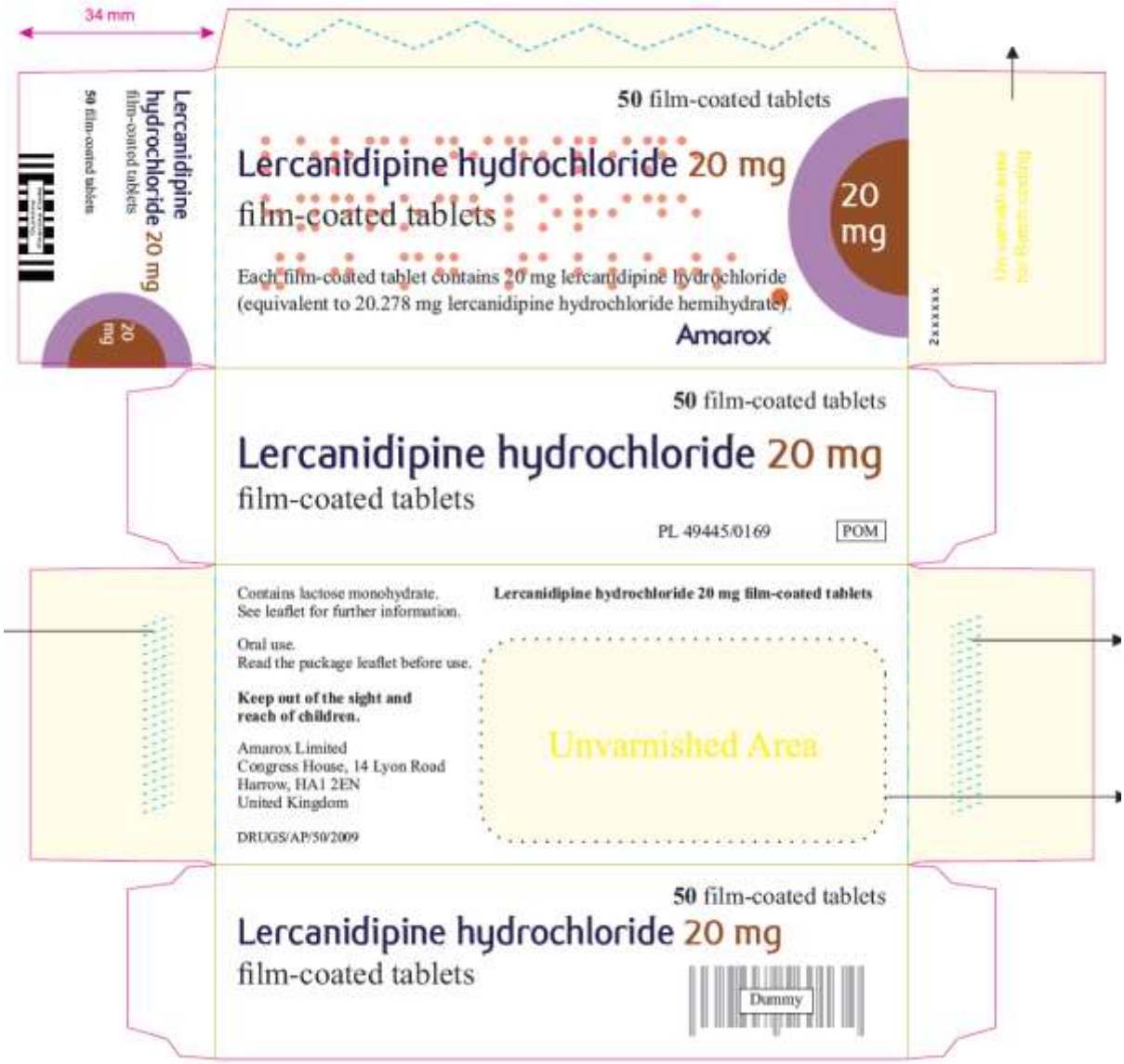
Lot:
EXP.:


20 mm
Lercanidipine hydrochloride 20 mg
film-coated tablets
28 film-coated tablets
20 mg
28 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
20 mg
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
Amarox
Unvarnish Area for Batch coding details
xxxxxx2
Lercanidipine hydrochloride 20 mg
film-coated tablets
28 film-coated tablets
PL 49445/0169
POM
28 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
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.
DRUGS/AP/50/2009
Unvarnished Area
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
Dummy

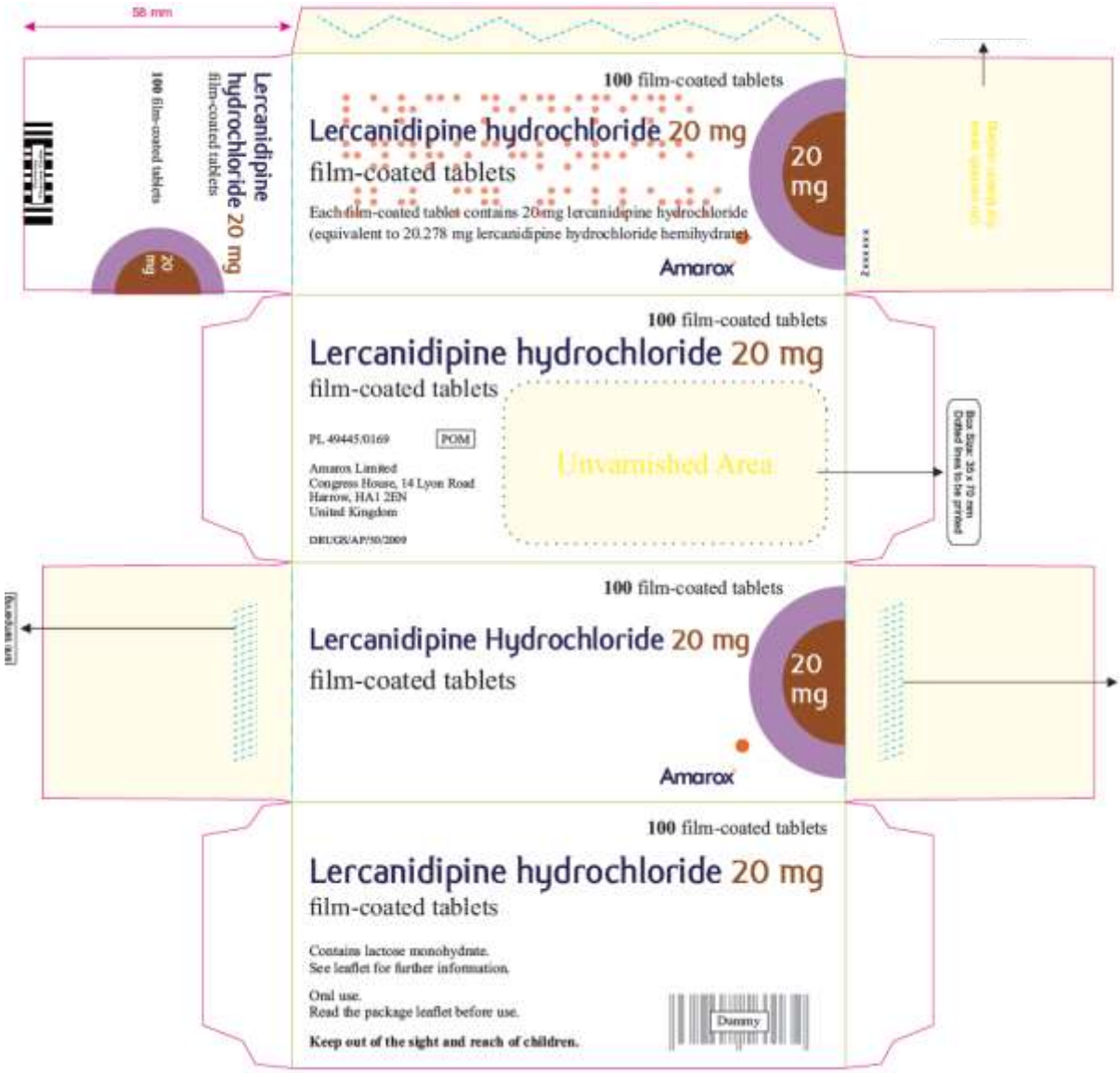

20 mm
28 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
20 mg
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
Amarox
Unvarnish Area for Batch coding details
2xxxxxx
PL 49445/0169
POM
DRUGS/AP/50/2009
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.
Amarox Limited
Congress House,
14 Lyon Road
Harrow, HA1 2EN
United Kingdom
Unvarnished Area
Dummy

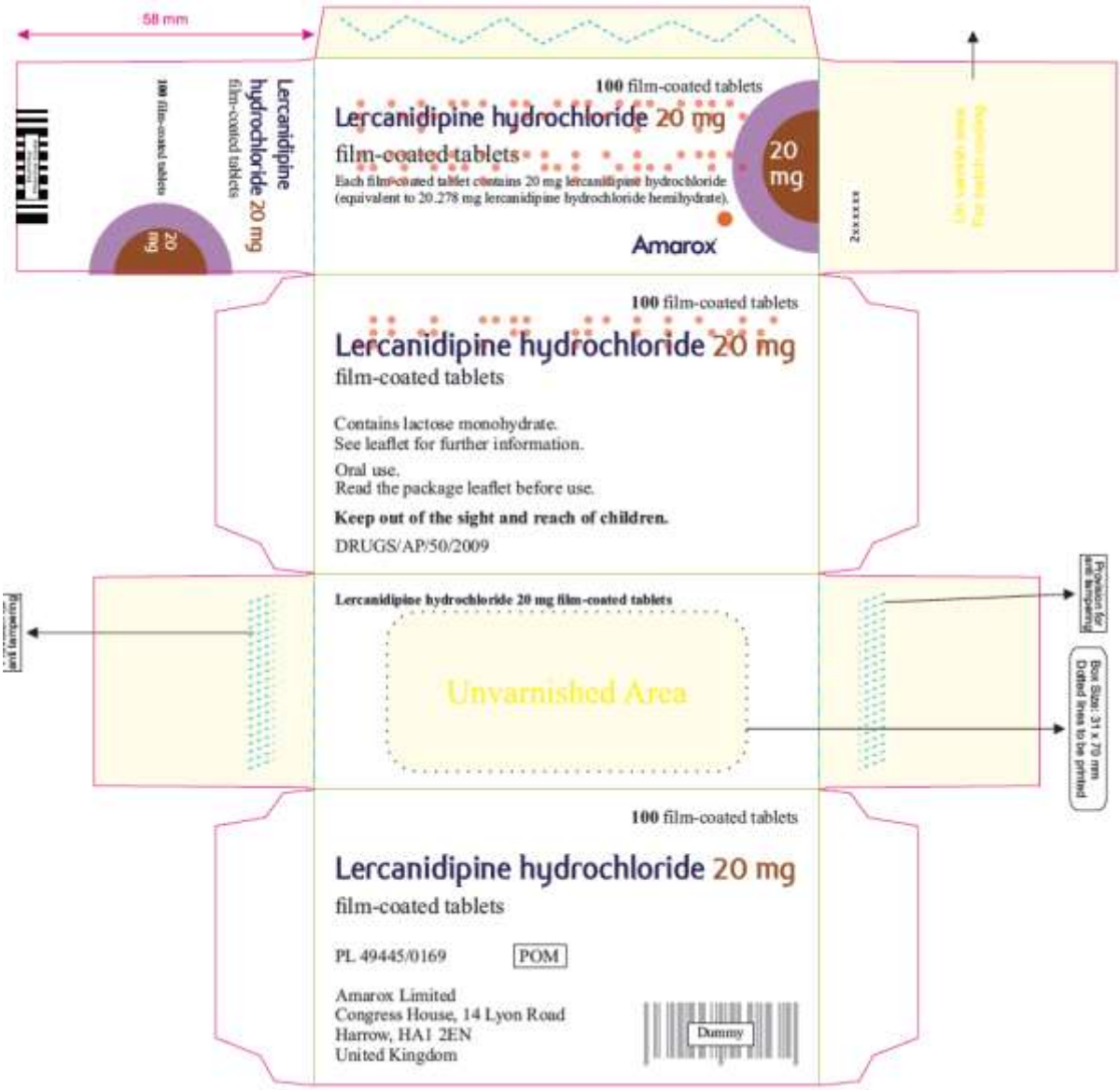

24 mm
30 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
20 mg
Each film-coated tablet contains 20 mg lercanidipine hydrochloride
(equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
Amarox
Un varnish area for Batch coding
2xxxxxx
30 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
PL 49445/0169
POM
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.
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
DRUGS/AP/50/2009
Lercanidipine hydrochloride 20 mg film-coated tablets
Unvarnished Area
30 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Dummy

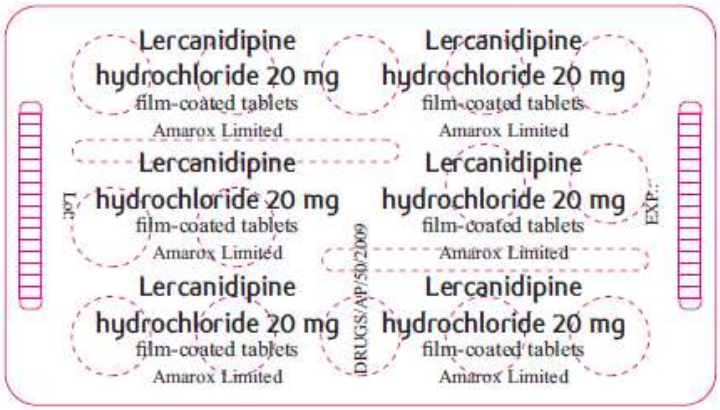

24 mm
30 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
20 mg
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
Amarox
2xxxxxx
Un varnish area for Batch coding
30 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
PL 49445/0169
POM
Lercanidipine hydrochloride 20 mg film-coated tablets
Unvarnished Area
Dummy
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.
DRUGS/AP/50/2009
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom

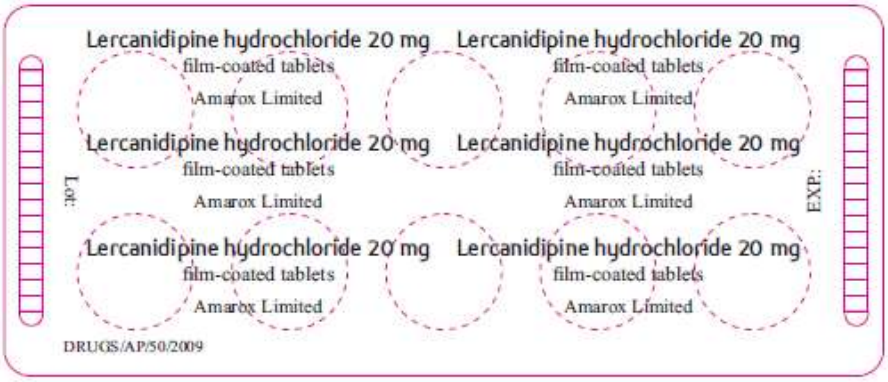

34 mm
Lercanidipine hydrochloride 20 mg
film-coated tablets
50 film-coated tablets
20 mg
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
Amarox
20 mg
2xxxxxx
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
PL 49445/0169
POM
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.
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
DRUGS/AP/50/2009
Lercanidipine hydrochloride 20 mg film-coated tablets
Unvarnished Area
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Dummy

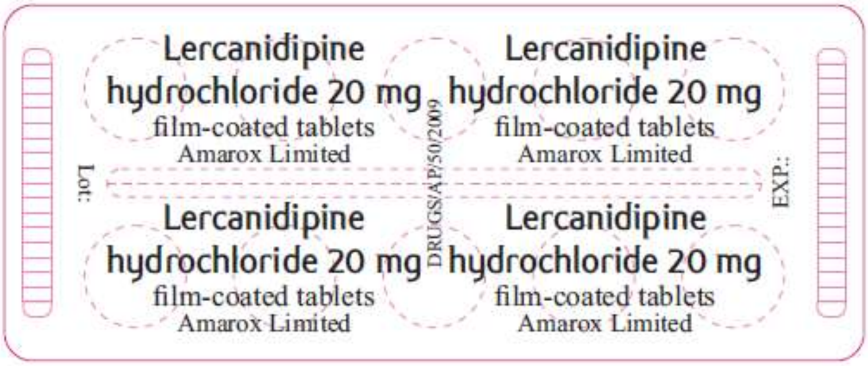

34 mm
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
20 mg
Amarox
Un varnish area for Batch coding
2xxxxxx
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
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.
DRUGS/AP/50/2009
Lercanidipine hydrochloride 20 mg film-coated tablets
Unvarnished Area
Dummy
50 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
PL 49445/0169
POM

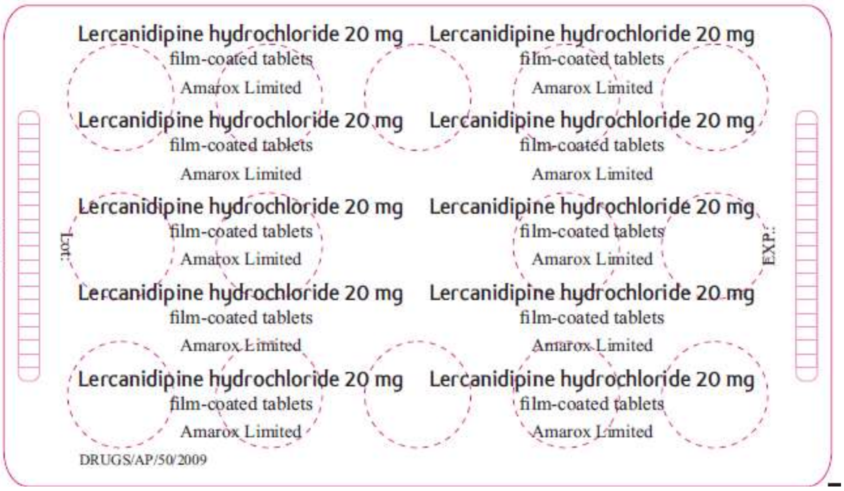

58 mm
100 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
20 mg
Each film-coated tablet contains 20mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate)
Amarox
PL 49445/0169
POM
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
DRUGS/AP/30/2009
Unvarnished Area
Box Size: 35 x 70 mm
Dotted lines to be printed
Lercanidipine Hydrochloride 20 mg
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.
Dummy


58 mm
100 film-coated tablets
Lercanidipine hydrochloride 20 mg
film-coated tablets
Each film-coated tablet contains 20 mg lercanidipine hydrochloride (equivalent to 20.278 mg lercanidipine hydrochloride hemihydrate).
20 mg
Amarox
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.
DRUGS/AP/50/2009
Unvarnished Area
PL 49445/0169
POM
Amarox Limited
Congress House, 14 Lyon Road
Harrow, HA1 2EN
United Kingdom
Dummy


Lercanidipine hydrochloride 20 mg film-coated tablets
Amarox Limited
LOT
EXP
DRUGS/AP/50/2009


Lercanidipine hydrochloride 20 mg
film-coated tablets
Amarox Limited
Lot:
EXP.:
DRUGS/AP/50/2009


Lercanidipine hydrochloride 20 mg
film-coated tablets
Amarox Limited
Lot:
EXP.:
DRUGS/AP/50/2009


Lercanidipine hydrochloride 20 mg
film-coated tablets
Amarox Limited
Lot:
EXP.:
DRUGS/AP/50/2009

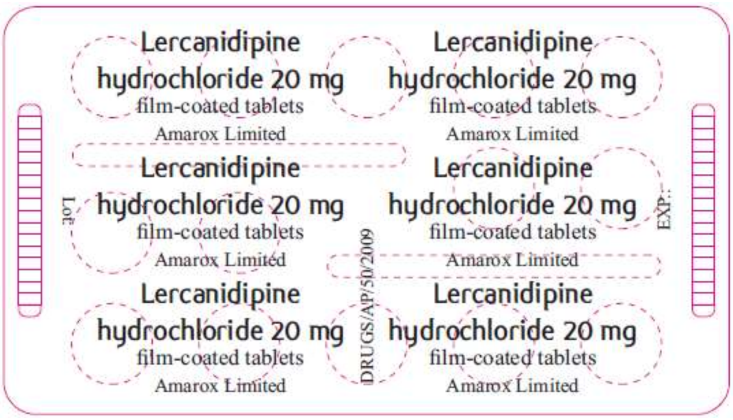

Lercanidipine hydrochloride 20 mg
film-coated tablets
Amarox Limited
Lot:
EXP.:
DRUGS/AP/50/2009

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**