Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Fenhuma 100 microgram sublingual tablets
Fenhuma 200 microgram sublingual tablets
Fenhuma 300 microgram sublingual tablets
Fenhuma 400 microgram sublingual tablets
Fenhuma 600 microgram sublingual tablets
Fenhuma 800 microgram sublingual tablets

fentanyl citrate

PL 25258/0355-0360

Glenmark Pharmaceuticals Europe Limited

LAY SUMMARY

Fenhuma 100 microgram sublingual tablets
Fenhuma 200 microgram sublingual tablets
Fenhuma 300 microgram sublingual tablets
Fenhuma 400 microgram sublingual tablets
Fenhuma 600 microgram sublingual tablets
Fenhuma 800 microgram sublingual tablets
fentanyl citrate

This is a summary of the Public Assessment Report (PAR) for Fenhuma 100, 200, 300, 400, 600 and 800 microgram sublingual 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 Fenhuma tablets in this lay summary for ease of reading.

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

What are Fenhuma 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 in the United Kingdom (UK) called Abstral 100, 200, 300, 400, 600 and 800 microgram sublingual tablets.

Fenhuma tablets are used for adults who are already regularly taking strong pain-relieving medicine (opioids) for their persistent cancer pain but require treatment for their breakthrough pain. Breakthrough pain is pain which occurs suddenly, even though the patient has taken or used their usual opioid pain-relieving medicine.

How do Fenhuma tablets work?
These medicines contain the active ingredient fentanyl, which belongs to a class of medicines called opioids, which are ‘pain relievers’.

How are Fenhuma tablets used?
The pharmaceutical form of this medicine is a sublingual tablet and the route of administration is sub-lingual (under the tongue).

The patient’s doctor should discuss with them how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

These products should only be used by the patient according to their doctor’s instructions. They should not be used by anyone else as they could present a serious risk to their health, especially in children.

For Fenhuma tablets to work successfully, a doctor will need to identify the most appropriate dose for treating the patient’s breakthrough pain. Fenhuma tablets are available in a range of strengths. The patient may need to try different strengths of Fenhuma tablets over a number

of episodes of breakthrough pain to find the most appropriate dose. A doctor will help the patient to do this and will work with them to find the best dose to use.

If the patient does not get adequate pain relief from one dose, their doctor may ask them to take an extra dose to treat an episode of breakthrough pain. The patient should not take a second dose unless their doctor tells them to, as this may result in overdose.

Sometimes a doctor may advise the patient to take a dose which consists of more than one tablet at a time. The patient should only do this if directed by their doctor.

The patient should wait at least 2 hours from taking their last dose before treating their next episode of breakthrough pain with Fenhuma tablets.

Once the patient and their doctor have found a dose of Fenhuma tablets that controls their breakthrough pain, they should take this dose no more than four times a day. A dose of Fenhuma tablets may consist of more than one tablet.

If the patient thinks that the dose of Fenhuma tablets that they are using is not controlling their breakthrough pain satisfactorily, they should tell their doctor, as the doctor may need to adjust the dose.

Fenhuma tablets should be used sublingually. This means that the tablet should be placed under the tongue where it dissolves rapidly in order to allow fentanyl to be absorbed across the lining of the mouth. Once absorbed, fentanyl starts to work to relieve pain.

The tablet should be placed under the tongue as far back as possible and the patient should let it dissolve completely. It is important that the patient does not suck, chew or swallow the tablet. They should not drink or eat anything until the tablet has completely dissolved under the tongue.

For further information on how Fenhuma 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 these medicines 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 Fenhuma tablets have been shown in studies?
As Fenhuma 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 Fenhuma 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 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.

As Fenhuma 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 Fenhuma tablets approved?
It was concluded that, Fenhuma 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 it can be approved for use.

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

The following safety concerns have been recognised for Fenhuma tablets:
Important identified risks:
- Drug abuse
- Drug diversion
- Drug dependence
- Misuse
- Off-label use
- Medication errors
- Overdose
- Respiratory depression
- Local tolerability

Important potential risks:
- Cardiovascular depression
- Brain lesion
- Serotonin syndrome induced by interaction between fentanyl and serotonergic drugs
- Accidental exposure

Missing information:
- Use in fertility, pregnancy and lactation
- Use in children and adolescents
- Use in patients with cardiac, renal or hepatic impairment
- Long-term use

Other information about Fenhuma tablets
Marketing Authorisations for Fenhuma tablets were granted in the UK on 18 January 2022.

The full PAR for Fenhuma tablets follows this summary.

This summary was last updated in March 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 Fenhuma 100, 200, 300, 400, 600 and 800 microgram sublingual tablets (PL 25258/0355-0360) could be approved.

The products are approved for the following indication:
Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. Breakthrough pain is a transient exacerbation of otherwise controlled chronic background pain.

These medicines contain the active substance fentanyl (as citrate). Fentanyl is a potent μ-opioid analgesic with rapid onset of analgesia and short duration of action. Fentanyl is approximately 100-fold more potent than morphine as an analgesic. Secondary effects of fentanyl on central nervous system (CNS), respiratory and gastro-intestinal function are typical of opioid analgesics and are considered to be class effects. These can include respiratory depression, bradycardia, hypothermia, constipation, miosis, physical dependence and euphoria.

These applications were approved under Regulation 51B of The Human Medicines Regulations 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended), as generic medicines of suitable reference medicinal products, Abstral 100, 200, 300, 400, 600 and 800 microgram sublingual tablets, that have been licensed within the United Kingdom (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.

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.

National marketing authorisations were granted in the UK on 18 January 2022.

II QUALITY ASPECTS

II.1 Introduction

These products consist of sublingual tablets containing 100, 200, 300, 400, 600 and 800 micrograms fentanyl (as citrate).

In addition to fentanyl, these products also contain the excipients mannitol (E421), silicified microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

The finished products are packaged in child-resistant aluminium perforated or non-perforated blisters (PA/Al/PVC) thermo-sealed to a foil (Al/PET), contained in a cardboard outer carton. The products are available in pack sizes of 10, 10 x 1, 30 and 30 x 1 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.

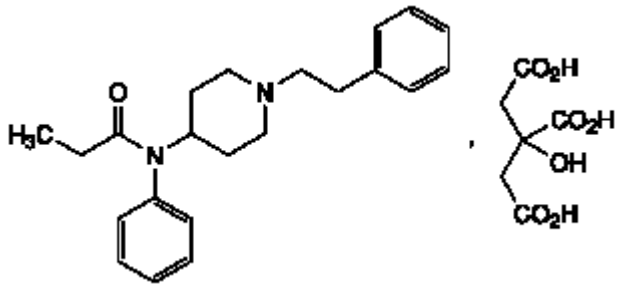
II.2 ACTIVE SUBSTANCE

rINN: Fentanyl citrate

Chemical Name: N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl] propanamide dihydrogen 2-hydroxypropane-1,2,3-tricarboxylate

Molecular Formula: $C_{22}H_{28}N_2O.C_6H_8O_7$

Chemical Structure:



Molecular Weight: 528.6 (salt), 336.5 (base)

Appearance: White or almost white powder

Solubility: Soluble in water; freely soluble in methanol and sparingly soluble in ethanol

Fentanyl citrate 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 PRODUCT

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.

No excipients of animal or human origin are used in the final products.
Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

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 36 months, with no special storage conditions, is acceptable.

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 fentanyl citrate 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 fentanyl citrate 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.

Study 1
This study was a single oral dose, randomised, open label, two treatment, two period, two sequence, cross-over bioequivalence study comparing the test product Fenhuma 300 microgram sublingual tablets versus the reference product, Abstral 300 microgram sublingual tablets, in subjects under fasted conditions.

Subjects were administered a single dose of 300 micrograms of the test or reference product (1 x 300 microgram sublingual tablet), after an overnight fast of at least 10 hours. Blood samples were taken pre-dose and up to 32 hours post dose, with a washout period of 7 days between the treatment periods.

A summary of the pharmacokinetic results are presented below:

Pharmacokinetic data:

Pharmacokinetic parameter	Arithmetic Means ±SD	
	Test Product	Reference Product
$AUC_{(0-t)}$ (pg·h/mL)	3358.05±1631.23	3398.87±1657.86
$AUC_{(0-\infty)}$ (pg·h/mL)	4058.02±2355.61	3981.50±2201.74
C_{max} (pg/mL)	640.85±208.91	664.21±213.41
t_{max} [1] (hours)	1.00 (0.33 – 2.50)	1.00 (0.33 – 2.00)

[1] Median (Min, Max)

Bioequivalence evaluation:

Pharmacokinetic parameter	Geometric Mean Ratio Test/Ref	Confidence Intervals (%)	CV(%)[1]
AUC(0-t)	**100.04**	95.26 - 105.07	12.30
Cmax	**96.93**	89.82 - 104.60	19.11

[1] Estimated from the Residual Mean Squares

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 strengths of the product meet the biowaiver criteria specified in the current bioequivalence guideline, the results and conclusions from the bioequivalence study on the 300 microgram 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 Regulation 182 of The Human Medicines Regulations 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.

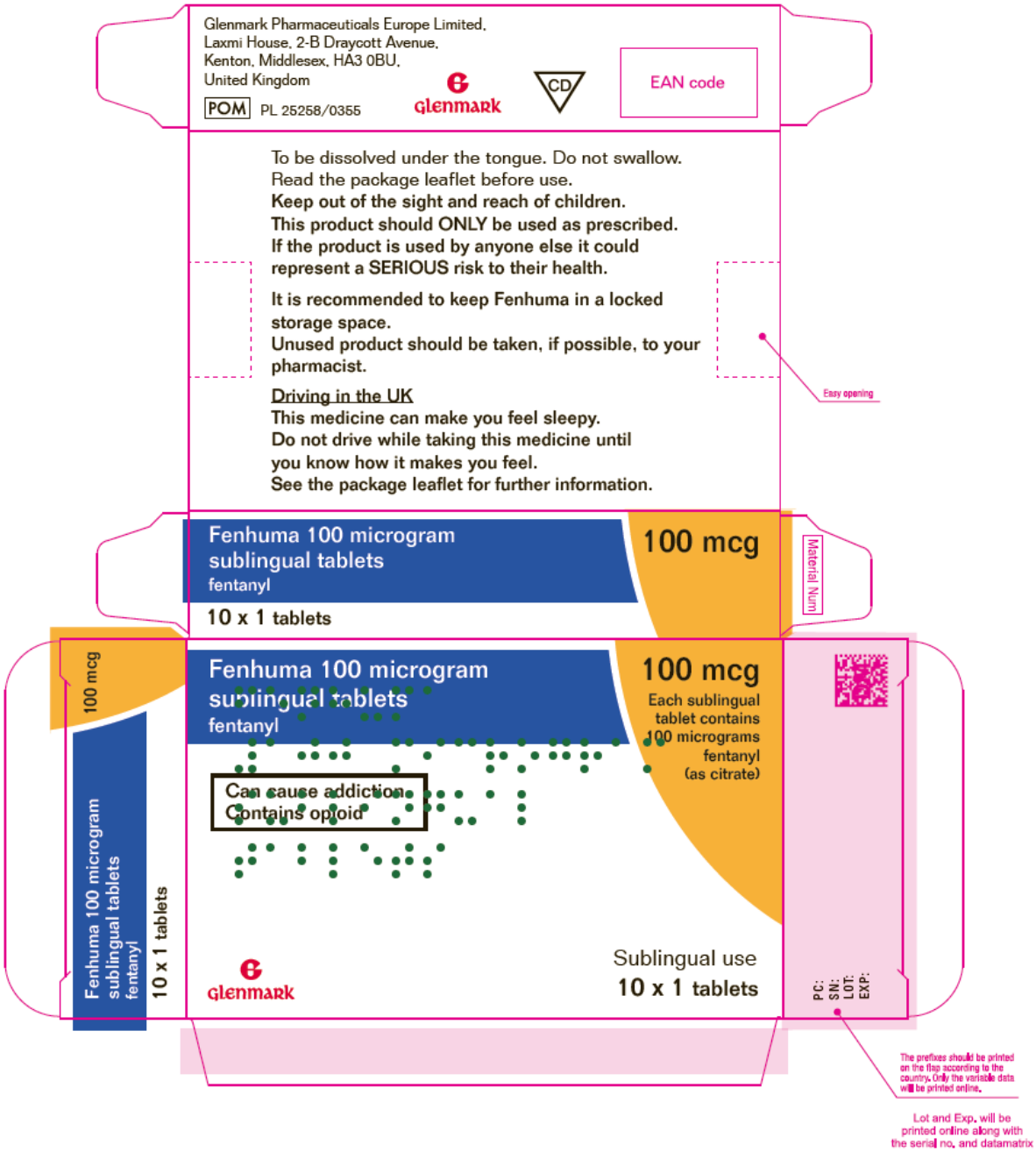
The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to the reference product PIL for content and the PIL for Valganciclovir Kern Pharma 450 mg tablets (Kern Pharma, S.L) for layout. The bridging report submitted by the applicant is acceptable.

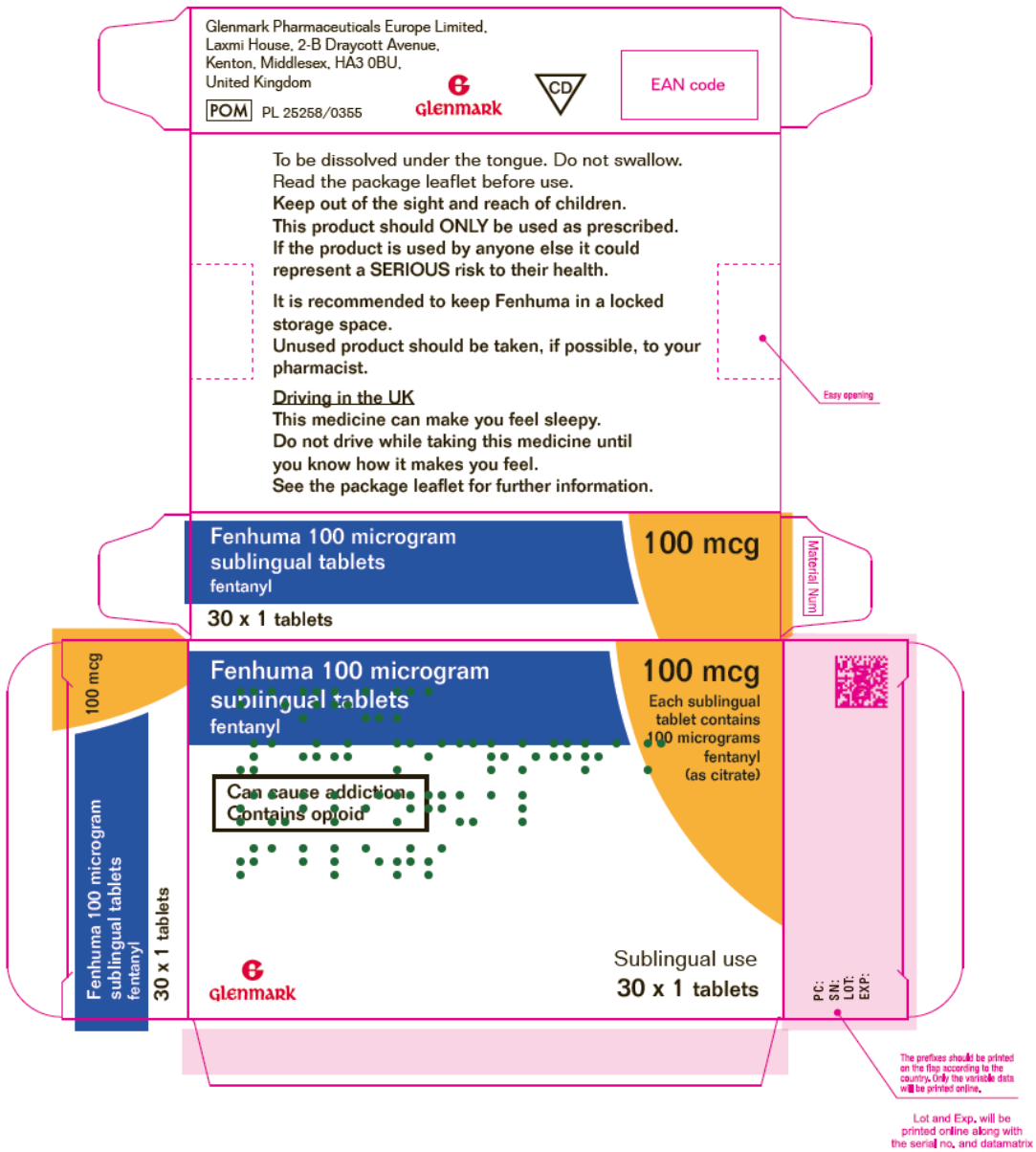
VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

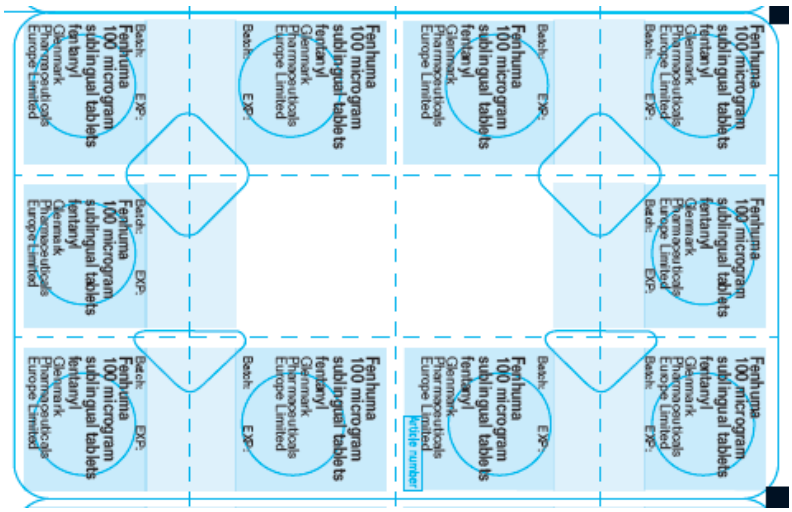
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with fentanyl citrate is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

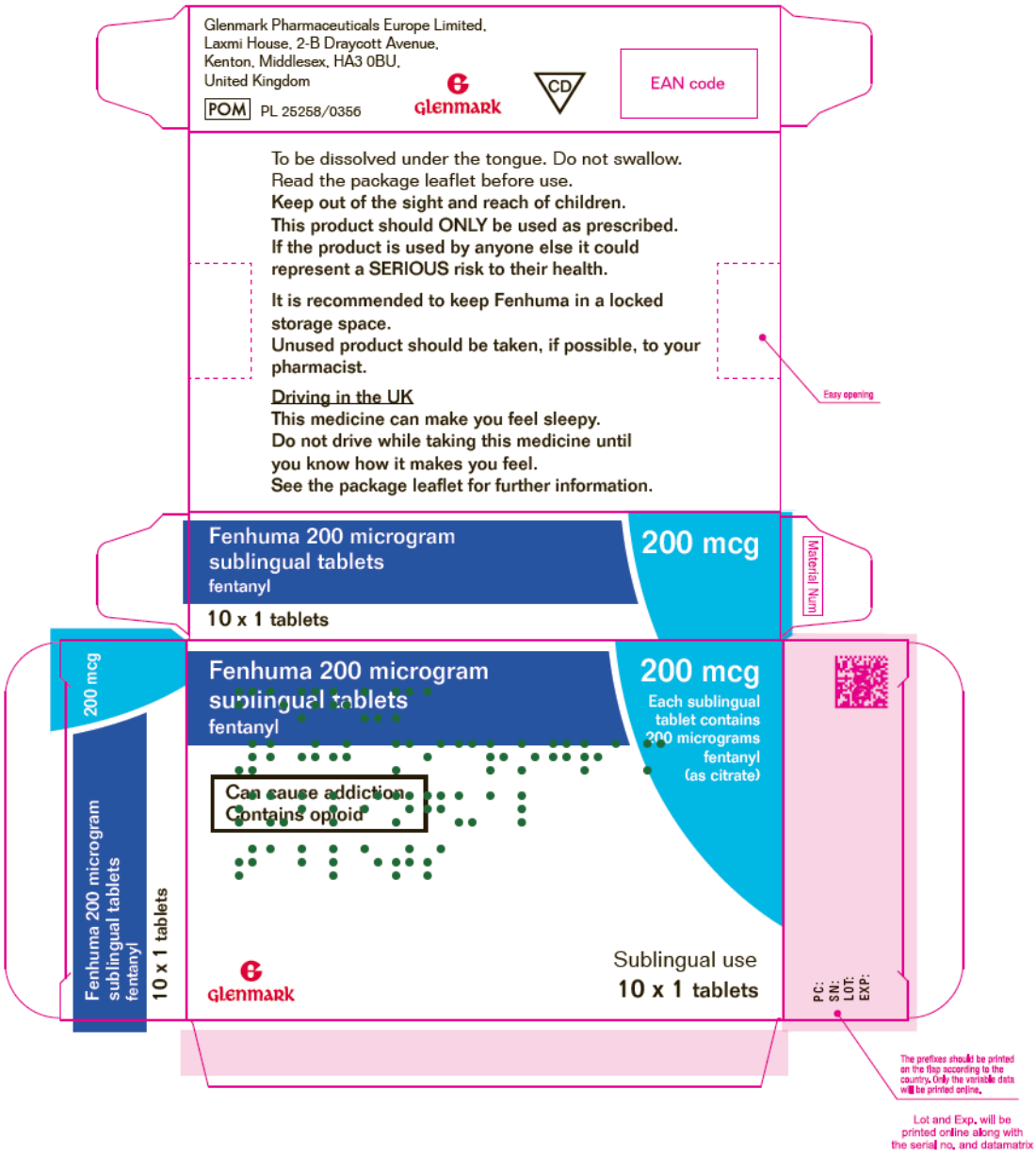
The Summaries of Product Characteristics (SmPCs), PIL and labelling are satisfactory, in line with current guidelines and consistent with the reference products.
In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

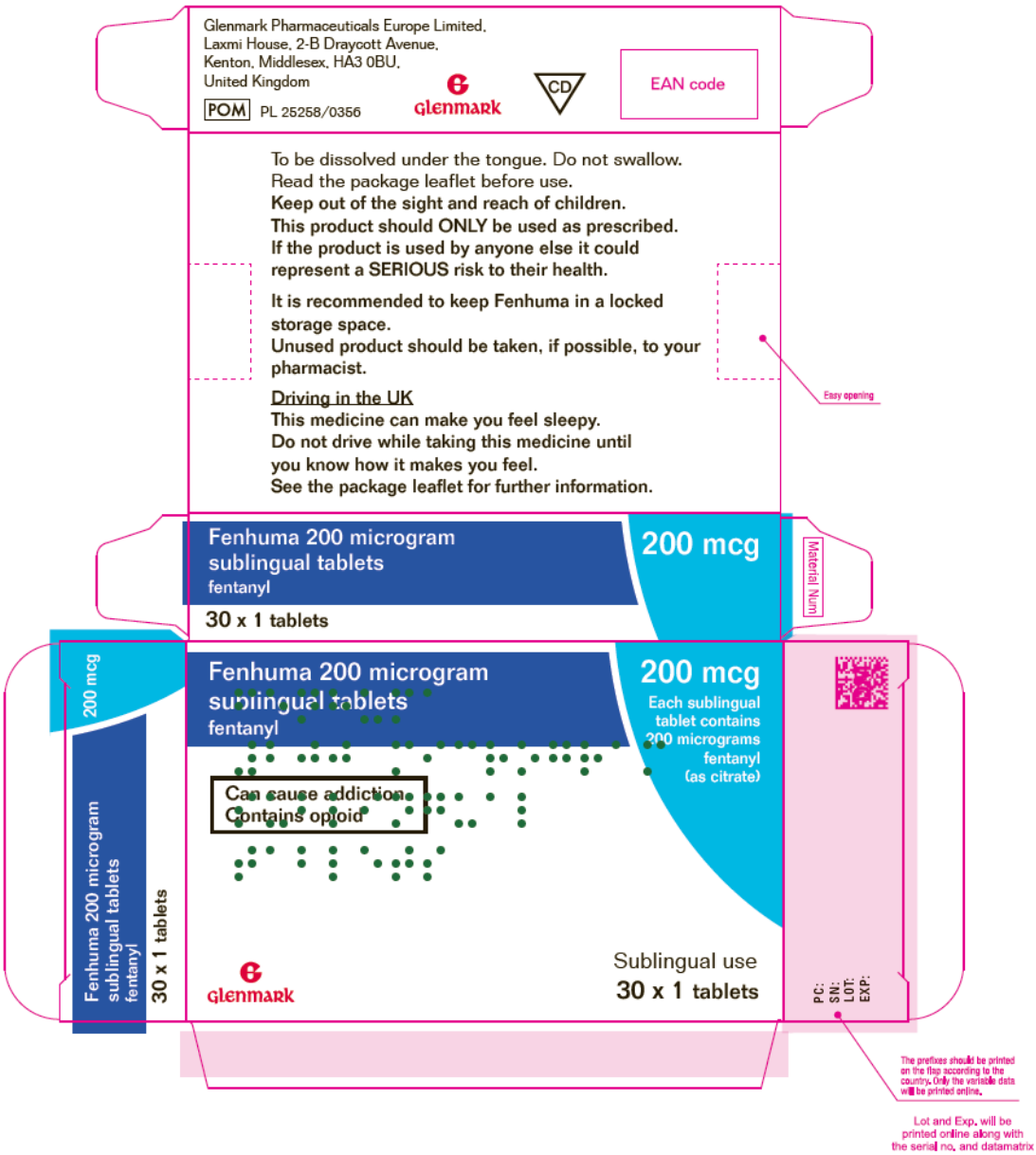
Representative copies of the labels at the time of licensing are provided below.

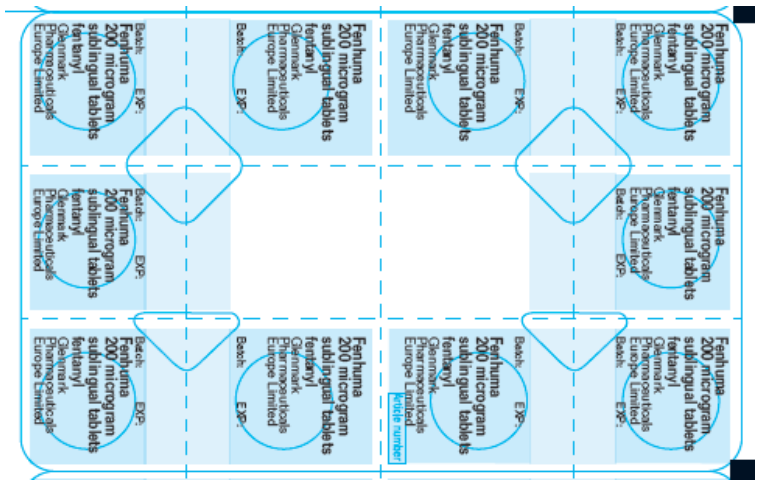


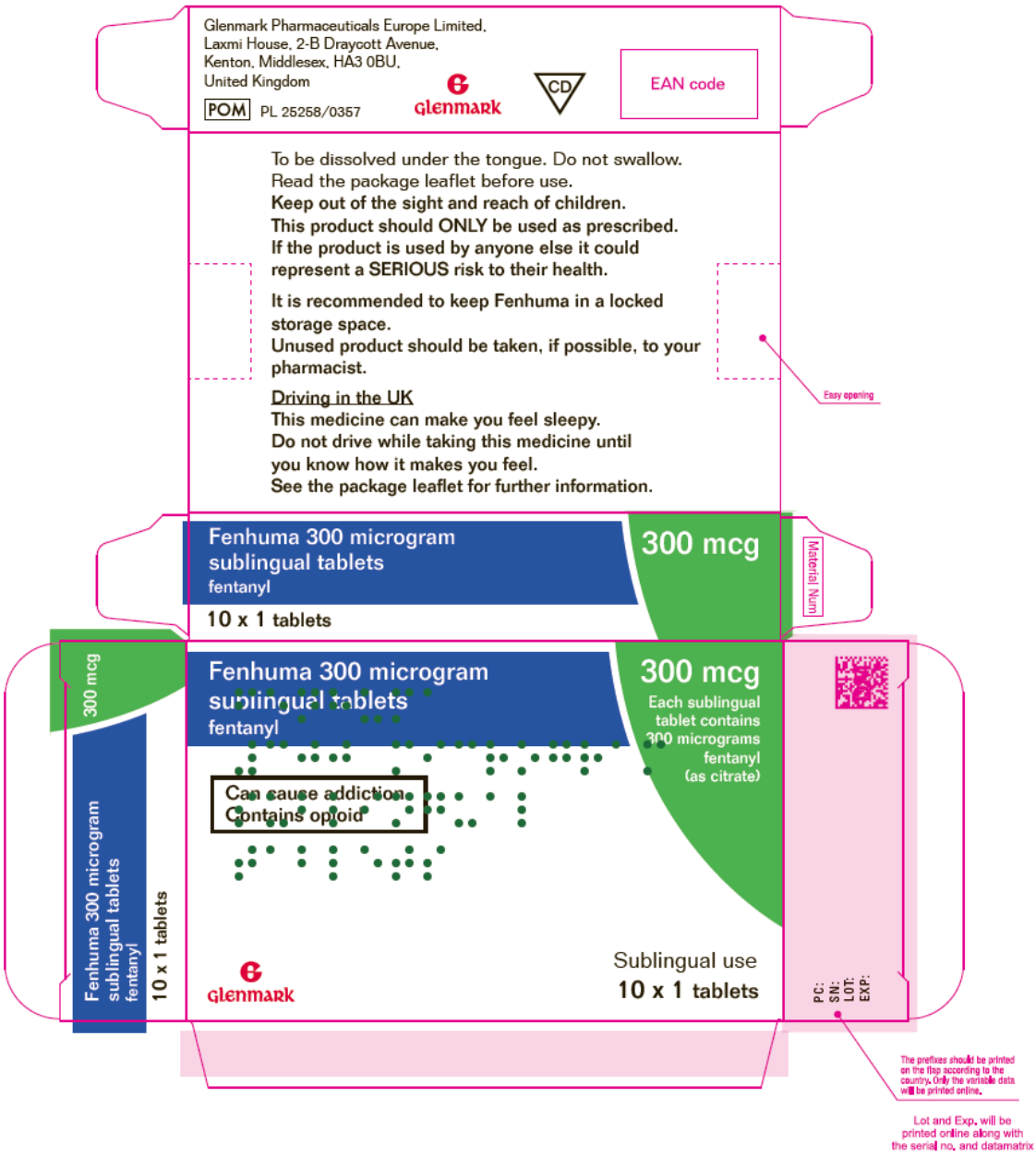

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0355
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 100 microgram sublingual tablets
fentanyl
30 x 1 tablets
100 mcg
Material Num
100 mcg
Fenhuma 100 microgram sublingual tablets
fentanyl
Can cause addiction
Contains opioid
100 mcg
Each sublingual tablet contains 100 micrograms fentanyl (as citrate)
Fenhuma 100 microgram sublingual tablets fentanyl
30 x 1 tablets
glenmark
Sublingual use
30 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

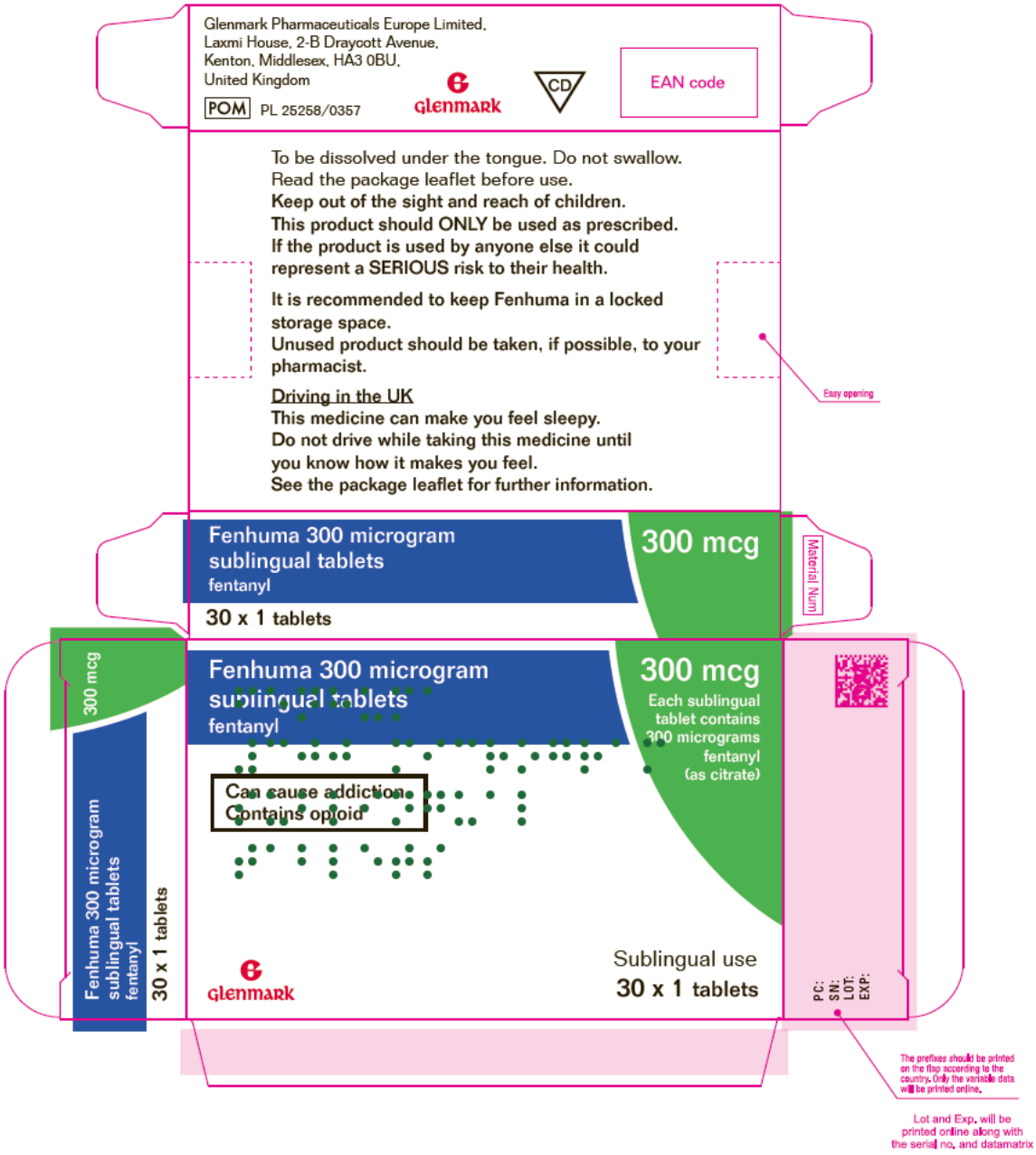


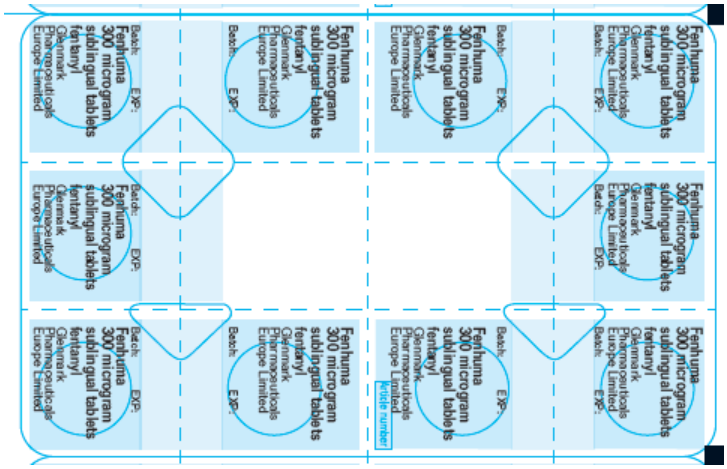

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0356
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 200 microgram sublingual tablets
fentanyl
10 x 1 tablets
200 mcg
Material Num
200 mcg
Fenhuma 200 microgram sublingual tablets
fentanyl
Fenhuma 200 microgram sublingual tablets fentanyl
10 x 1 tablets
Can cause addiction
Contains opioid
200 mcg
Each sublingual tablet contains 200 micrograms fentanyl (as citrate)
glenmark
Sublingual use
10 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

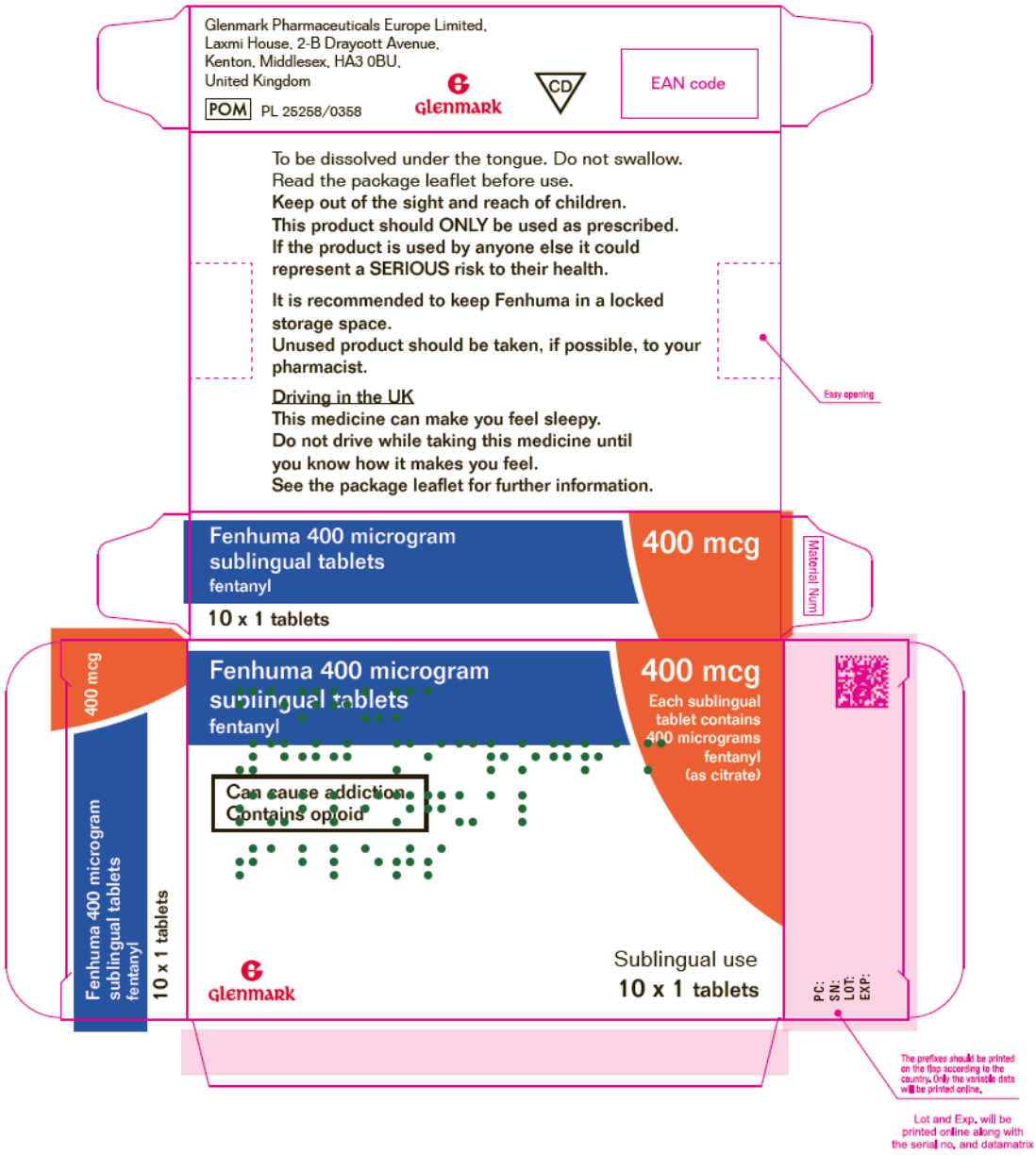

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0356
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 200 microgram sublingual tablets
fentanyl
30 x 1 tablets
200 mcg
Material Num
200 mcg
Fenhuma 200 microgram sublingual tablets fentanyl
30 x 1 tablets
Fenhuma 200 microgram sublingual tablets
fentanyl
Can cause addiction
Contains opioid
200 mcg
Each sublingual tablet contains 200 micrograms fentanyl (as citrate)
glenmark
Sublingual use
30 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

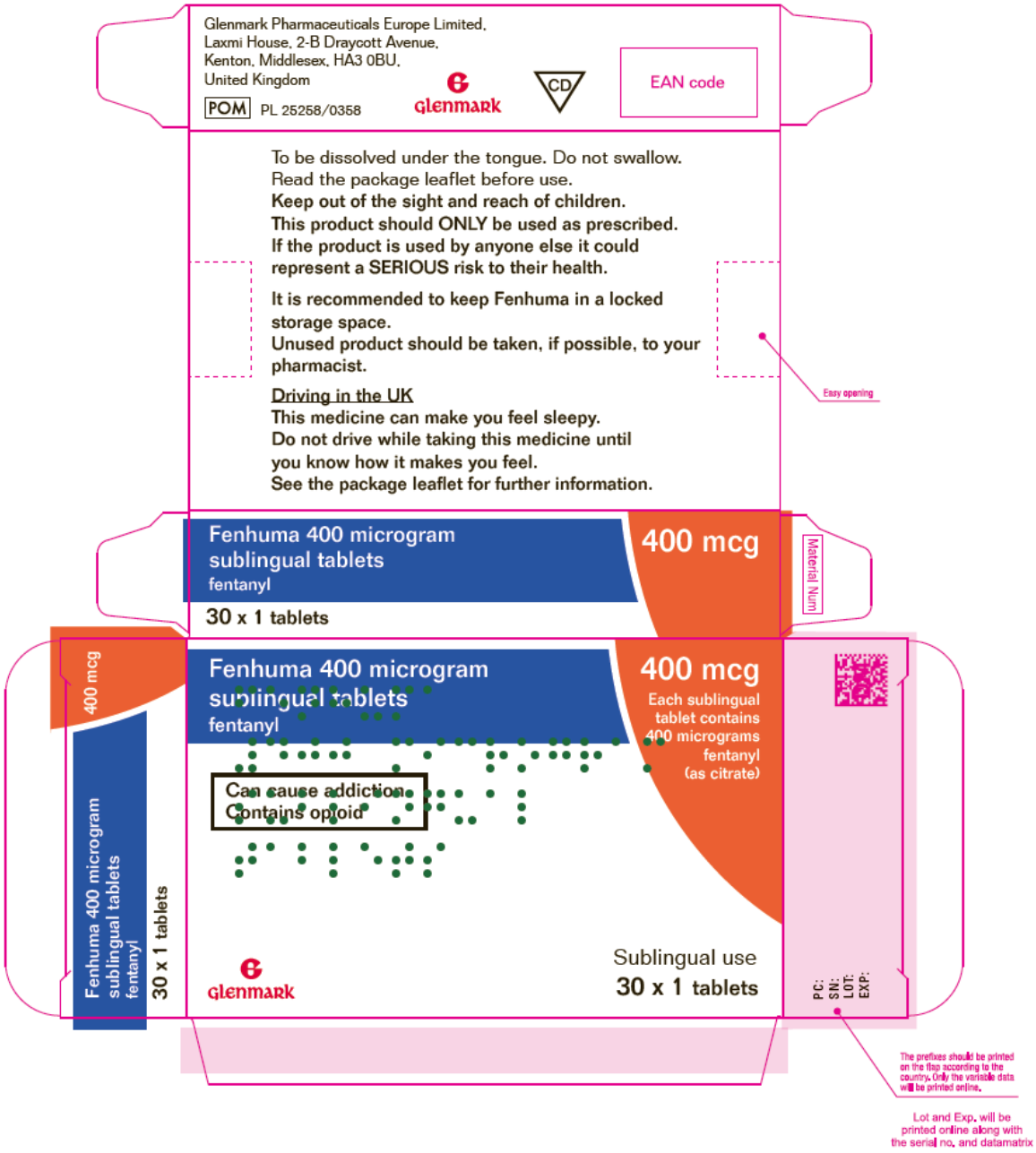

Fenhuma 200 microgram sublingual tablets fentanyl
Glenmark Pharmaceuticals Europe Limited
Batch:
EXP:

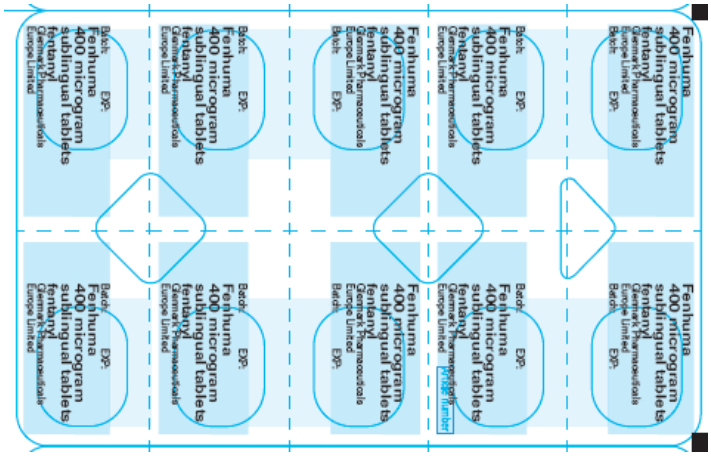

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0357
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 300 microgram sublingual tablets
fentanyl
10 x 1 tablets
300 mcg
Material Num
300 mcg
Fenhuma 300 microgram sublingual tablets
fentanyl
Can cause addiction
Contains opioid
300 mcg
Each sublingual tablet contains 300 micrograms fentanyl (as citrate)
Fenhuma 300 microgram sublingual tablets fentanyl
10 x 1 tablets
glenmark
Sublingual use
10 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

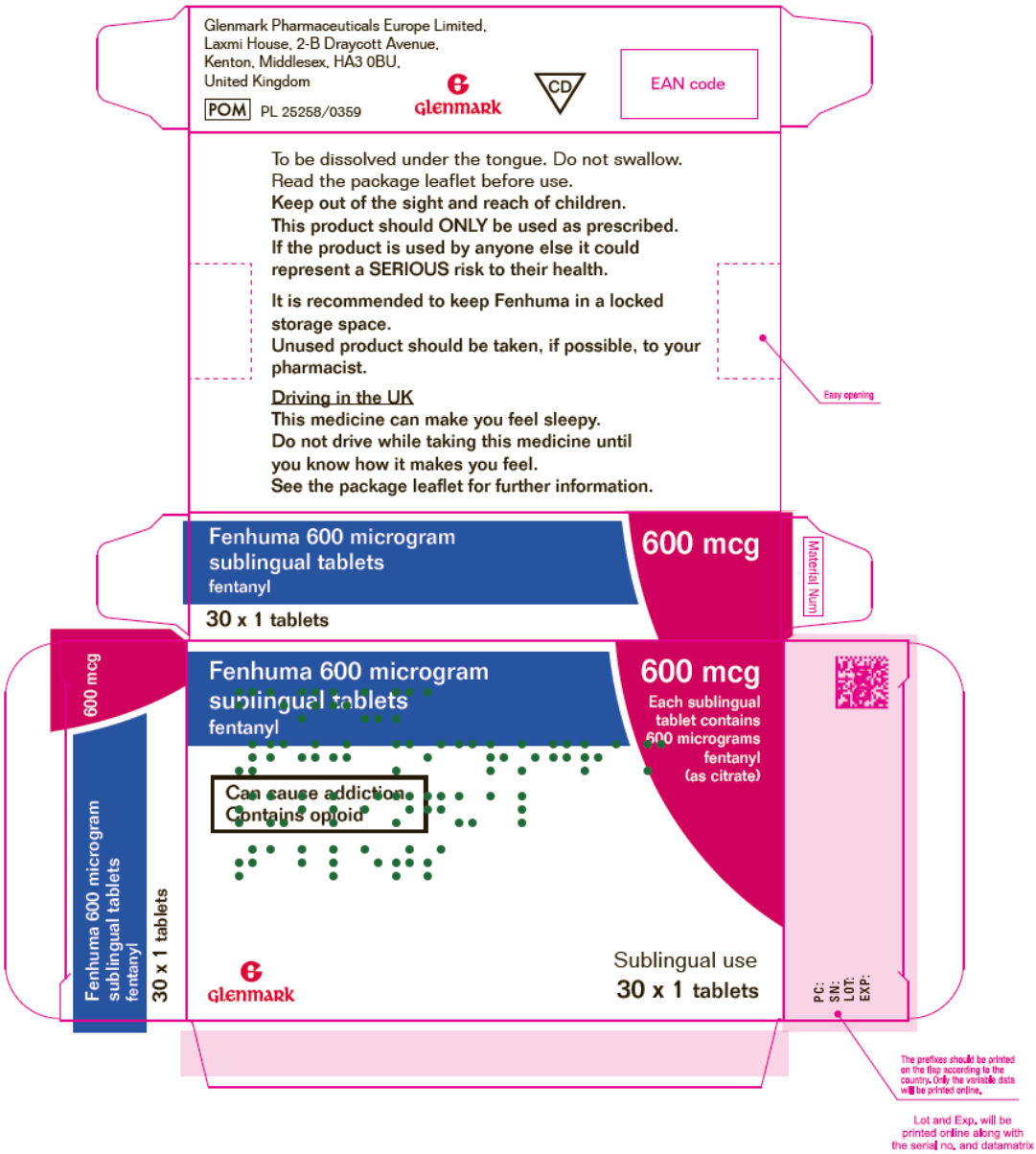

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0357
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 300 microgram sublingual tablets
fentanyl
300 mcg
30 x 1 tablets
Material Num
300 mcg
Fenhuma 300 microgram sublingual tablets
fentanyl
Can cause addiction
Contains opioid
300 mcg
Each sublingual tablet contains 300 micrograms fentanyl (as citrate)
Fenhuma 300 microgram sublingual tablets fentanyl
30 x 1 tablets
glenmark
Sublingual use
30 x 1 tablets
P.C:
S.N:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

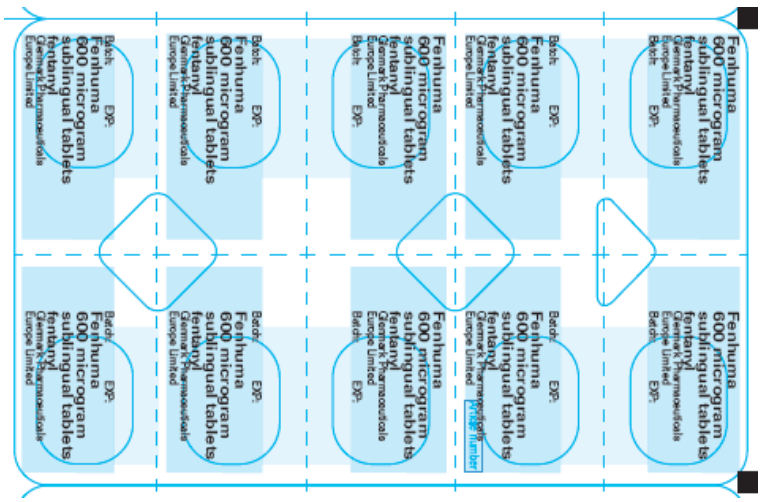


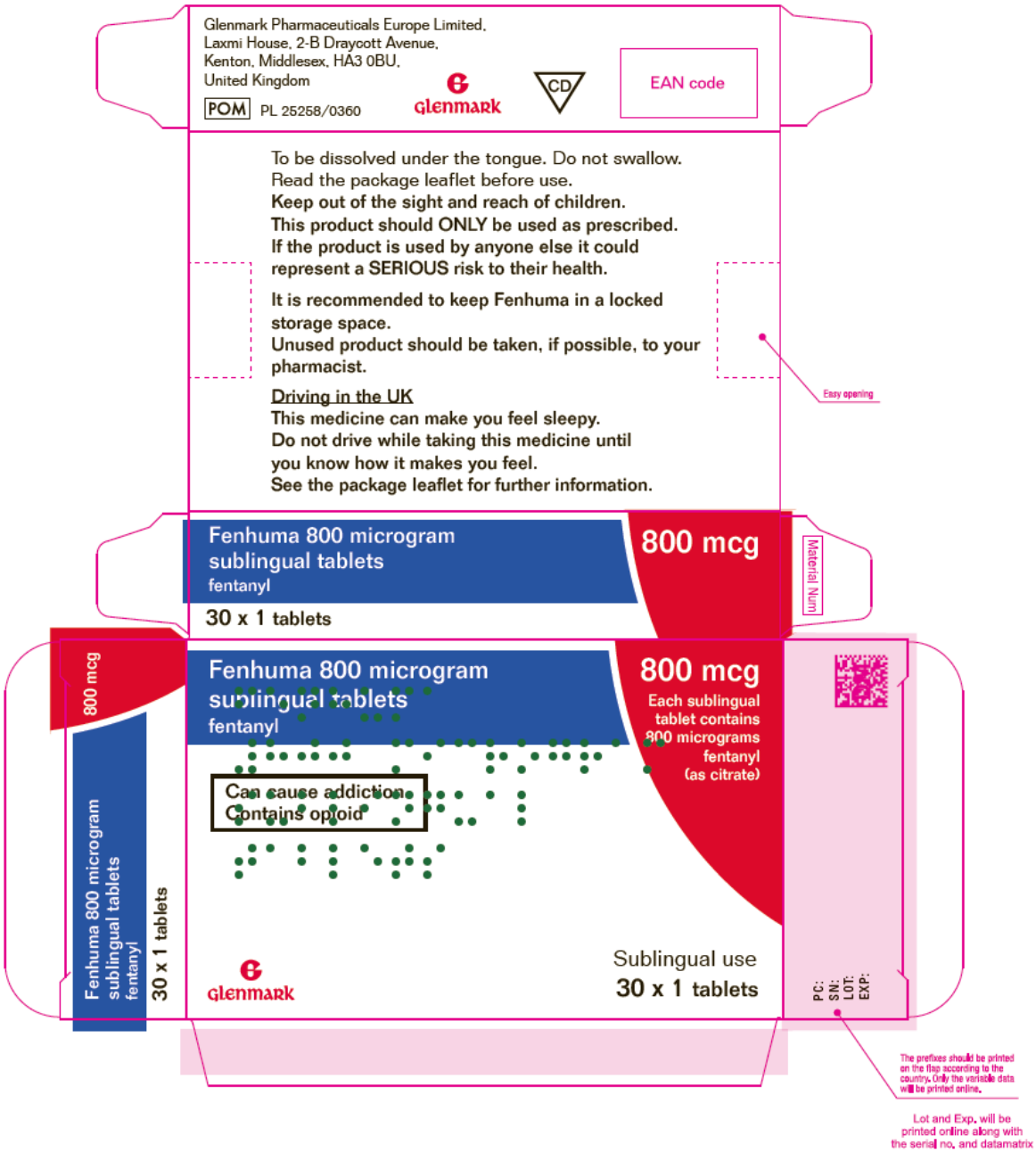

Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0358
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 400 microgram sublingual tablets
fentanyl
400 mcg
10 x 1 tablets
Material Num
400 mcg
Fenhuma 400 microgram sublingual tablets fentanyl
10 x 1 tablets
Fenhuma 400 microgram sublingual tablets
fentanyl
400 mcg
Each sublingual tablet contains 400 micrograms fentanyl (as citrate)
Can cause addiction
Contains opioid
glenmark
Sublingual use
10 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix


Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0358
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 400 microgram sublingual tablets
fentanyl
30 x 1 tablets
400 mcg
Material Num
400 mcg
Fenhuma 400 microgram sublingual tablets fentanyl
30 x 1 tablets
Fenhuma 400 microgram sublingual tablets
fentanyl
400 mcg
Each sublingual tablet contains 400 micrograms fentanyl (as citrate)
Can cause addiction
Contains opioid
glenmark
Sublingual use
30 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix




Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0359
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 600 microgram sublingual tablets
fentanyl
30 x 1 tablets
600 mcg
Material Num
600 mcg
Fenhuma 600 microgram sublingual tablets
fentanyl
Can cause addiction
Contains opioid
600 mcg
Each sublingual tablet contains 600 micrograms fentanyl (as citrate)
Fenhuma 600 microgram sublingual tablets fentanyl
30 x 1 tablets
glenmark
Sublingual use
30 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix




Glenmark Pharmaceuticals Europe Limited,
Laxmi House, 2-B Draycott Avenue,
Kenton, Middlesex, HA3 0BU,
United Kingdom
POM PL 25258/0360
glenmark
CD
EAN code
To be dissolved under the tongue. Do not swallow.
Read the package leaflet before use.
Keep out of the sight and reach of children.
This product should ONLY be used as prescribed.
If the product is used by anyone else it could represent a SERIOUS risk to their health.
It is recommended to keep Fenhuma in a locked storage space.
Unused product should be taken, if possible, to your pharmacist.
Driving in the UK
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the package leaflet for further information.
Easy opening
Fenhuma 800 microgram sublingual tablets
fentanyl
30 x 1 tablets
800 mcg
Material Num
800 mcg
Fenhuma 800 microgram sublingual tablets
fentanyl
30 x 1 tablets
Fenhuma 800 microgram sublingual tablets
fentanyl
800 mcg
Each sublingual tablet contains 800 micrograms fentanyl (as citrate)
Can cause addiction
Contains opioid
glenmark
Sublingual use
30 x 1 tablets
PC:
SN:
LOT:
EXP:
The prefixes should be printed on the flap according to the country. Only the variable data will be printed online.
Lot and Exp. will be printed online along with the serial no. and datamatrix

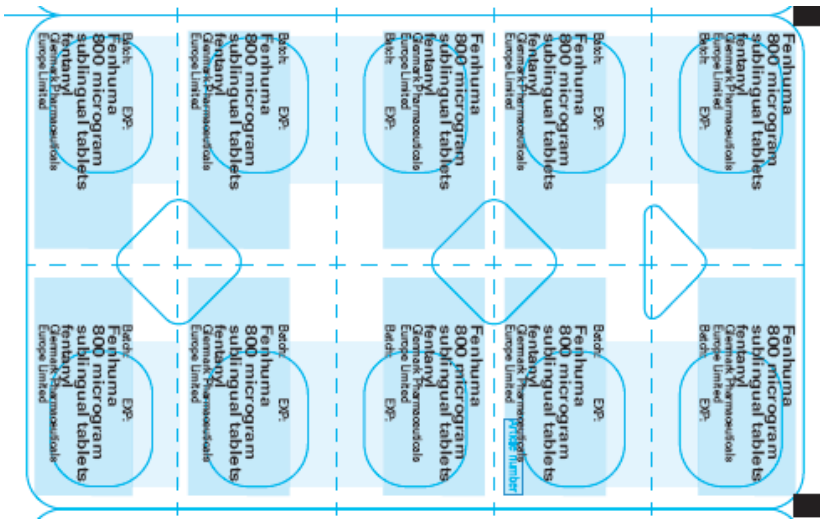


TABLE OF CONTENT OF THE PAR UPDATE

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 SmPCs and/or PIL available on the MHRA website.

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