Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Buvidal 160 mg prolonged-release solution for injection

(buprenorphine)

Product Licence Number: PLGB 42800/0008

LAY SUMMARY

Buvidal 160 mg prolonged-release solution for injection

(buprenorphine)

This is a summary of the Public Assessment Report (PAR) for Buvidal 160 mg prolonged-release solution for injection. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Buvidal 160 mg solution for injection in this lay summary for ease of reading.

For practical information about using Buvidal 160 mg solution for injection, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Buvidal 160 mg solution for injection and what is it used for?
Buvidal 8 mg, 16 mg, 24 mg, 32 mg, 64 mg, 96 mg and 128 mg solution for injection was originally authorised in the European Union through the Centralised procedure. This Centrally Authorised Product (CAP) has been automatically converted to Great Britain (consisting of England, Scotland and Wales) Marketing Authorisation.

Buvidal 160 mg solution for injection has been authorised by MHRA for Great Britain. In coming to its decision, MHRA has relied on a European Commission (EC) decision on 19 May 2021 (EMEA/H/C/004651/X/0008/G), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

This application is for a hybrid medicine. This means that the medicine is similar to a reference medicine already authorised in the European Union (EU) called Subutex 0.4 mg, 2 mg and 8 mg sublingual tablets, albeit with certain differences. In this case, Buvidal 160 mg solution for injection is for a different strength and formulation to the reference products.

Buvidal 160 mg solution for injection is a line extension of the existing products, Buvidal 8 mg, 16 mg, 24 mg, 32 mg, 64 mg, 96 mg, and 128 mg prolonged-release solution for injection. Taken together, the information submitted for this new strength and that already available for the other strengths of 8, 16, 24, 32, 64, 96 and 128 mg is sufficient to demonstrate a positive benefit risk for Buvidal 160 mg prolonged-release solution for injection in the indication listed.

Buvidal 160 mg solution for injection is used to treat opioid dependence in patients who are also receiving medical, social and psychological support. This product is intended for use in adults and adolescents aged 16 years or over.

How does Buvidal 160 mg solution for injection work?
Buvidal 160 mg solution for injection contains the active substance buprenorphine, which is a type of opioid medicine.

How is Buvidal 160 mg solution for injection used?
The pharmaceutical form of this medicine is solution for injection and the route of administration is subcutaneous (under the skin).

Buvidal must be given by healthcare professionals only. The patients' doctor will determine the best dose for the patient. During the patient's treatment, the doctor may adjust the dose, depending on how well the medicine works.

For further information on how Buvidal 160 mg solution for injection is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

What benefits of Buvidal 160 mg solution for injection have been shown in studies?
The clinical data submitted for the Buvidal 160 mg strength taken together with the information already available showed a positive benefit risk for patients in need of this higher dose.

What are the possible side effects of Buvidal 160 mg solution for injection?
The safety information from patients treated with the 160 mg strength is similar to that seen with the other strengths. However, an increased incidence of injection site adverse events was noted in these patients.

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC 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 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 this medicine.

Why was Buvidal 160 mg solution for injection approved?
It was concluded that Buvidal 160 mg solution for injection has been shown to be effective to treat opioid dependence in patients who are also receiving medical, social and psychological support. Buvidal 160 mg solution for injection is intended for use in adults and adolescents aged 16 years or over. Further, the side effects observed are considered to be typical for this type of treatment. Therefore, the MHRA decided that 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 Buvidal 160 mg solution for injection?
A Risk Management Plan (RMP) has been developed to ensure that Buvidal 160 mg solution for injection is used as safely as possible. Based on this plan, safety information has been included in the SmPC and the PIL, 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 Buvidal 160 mg solution for injection

A Marketing Authorisation for Buvidal 160 mg solution for injection was granted in the Great Britain (GB, consisting of England, Scotland and Wales) on 29 June 2021.

The full PAR for Buvidal 160 mg solution for injection follows this summary.

This summary was last updated in August 2021.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Buvidal 160 mg prolonged-release solution for injection (PLGB 42800/0008) could be approved.

The product is approved for treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.

Buprenorphine is an opioid partial agonist/antagonist which binds to the μ (mu) and κ (kappa) opioid receptors of the brain. Its activity in opioid maintenance treatment is attributed to its slowly reversible properties with the μ-opioid receptors which, over a prolonged period, might minimise the need of illicit opioids for patients with opioid dependence.

Opioid agonist ceiling effects were observed during clinical pharmacology studies in opioid-dependent persons.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 19 May 2021 (EMEA/H/C/004651/X/0008/G), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Reports, available on the EMA website.

This application was approved under Regulation 52B of The Human Medicines Regulation 2012, as amended (previously Article 10(3) of Directive 2001/83/EC, as amended), as a hybrid application. The application for Buvidal 160 mg prolonged-release solution for injection is a line extension of the existing products, Buvidal 8 mg, 16 mg, 24 mg, 32 mg, 64 mg, 96 mg and 128 mg prolonged release solution for injection.

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

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

A marketing authorisation was granted in the Great Britain (GB, consisting of England, Scotland and Wales) on 29 June 2021.

II. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

IV. NON-CLINICAL ASPECTS

The MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation is recommended.

VI. 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.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the applications in accordance with the requirements of Regulation 267 of the Human Medicines Regulations 2012, as amended (previously article 61(1) of Council Directive 2001/83/EC).

The PIL for Buvidal 160 mg prolonged-release solution for injection has been evaluated via a user consultation study in accordance with the requirements of Regulation 260(3) of The Human Medicines Regulation 2012, as amended (previously Article 59(3) of Council Directive 2001/83/EC). The results show that the PILs meet the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

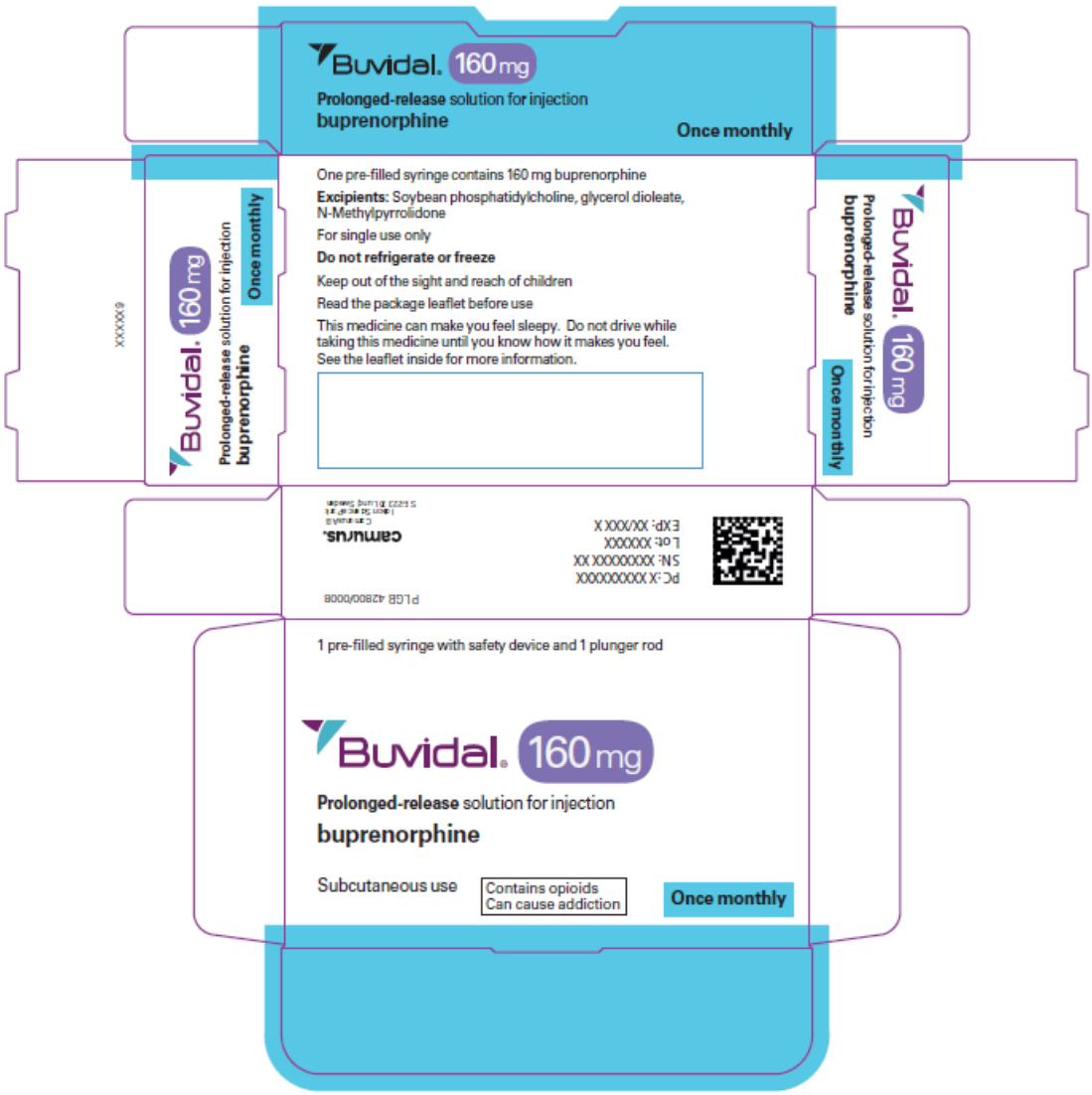
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

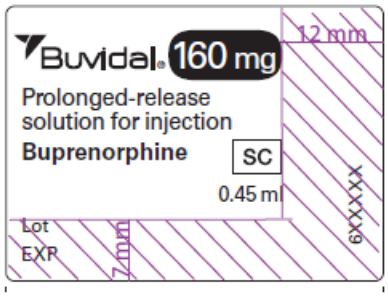
The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with Regulation 203(2) of The Human Medicines Regulation 2012, as

amended, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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





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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**