LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Buprenorphine G.L. Pharma (buprenorphine, buprenorphine hydrochloride)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Buprenorphine G.L. Pharma
buprenorphine, buprenorphine hydrochloride

Sublingual tablet, 0,2 mg, 0,4 mg

This is a summary of the public assessment report (PAR) for Buprenorphine G.L. Pharma. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Buprenorphine G.L. Pharma and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Temgesic.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

Buprenorphine G.L. Pharma is used to relieve severe pain after operations, in adults.

How does Buprenorphine G.L. Pharma work?

Buprenorphine G.L. Pharma belongs to a class of medicines called opioids, which are 'pain relievers'

How is Buprenorphine G.L. Pharma used?
The pharmaceutical form is sublingual tablet for sublingual use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Buprenorphine G.L. Pharma have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Temgesic. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Buprenorphine G.L. Pharma?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Buprenorphine G.L. Pharma approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Temgesic, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Buprenorphine G.L. Pharma?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics 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/reviewed continuously as well.

For more details, please see the full PAR for Buprenorphine G.L. Pharma on the following website: MRI - Home.

Other information about Buprenorphine G.L. Pharma

The full PAR for Buprenorphine G.L. Pharma can be found on the following website: MRI - Home. For more information about treatment with Buprenorphine G.L. Pharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-10.