LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Buprefarm
(buprenorphine)

SE/H/1630/X/06/G

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Summary Public Assessment Report

Buprefarm

(buprenorphine)

transdermal patch, 15 µg/h

This is a summary of the public assessment report (PAR) for Buprefarm. It explains how Buprefarm 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 Buprefarm.

For practical information about using Buprefarm, patients should read the package leaflet or contact their doctor or pharmacist.

What is Buprefarm and what is it used for?

Buprefarm is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but it is available in another pharmaceutical form as well as in different strengths.
The company has provided additional data to demonstrate the safety and efficacy of Buprefarm regarding this difference from the reference medicine.

The reference medicine for Buprefarm is Temgesic, 0, 2 mg, sublingual tablet. Buprefarm is used in the treatment of long-lasting pain that requires the use of a strong painkiller.

How does Buprefarm work?

Buprefarm contain the active ingredient buprenorphine which belongs to a group of medicines called strong analgesics or 'painkillers'. They have been prescribed for you by your doctor to relieve moderate, long-lasting pain that requires the use of a strong painkiller.
Buprefarm should not be used to relieve acute pain.

How is Buprefarm used?

The pharmaceutical form of Buprefarm is transdermal patch for transdermal 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.

What benefits of Buprefarm have been shown in studies?

Because Buprefarm is a hybrid application and is considered to be therapeutically equivalent, to the reference product Temgesic, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Buprefarm?

For the full list of all side effects reported with Buprefarm, see section 4 of the package leaflet.

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

Why is Buprefarm approved?

This medicine is similar to a reference medicine containing the same active substance, the company has provided additional data to demonstrate the safety and efficacy of Buprefarm regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Buprefarm's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Buprefarm?

A risk management plan has been developed to ensure that Buprefarm 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 for Buprefarm, 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.

Other information about Buprefarm

The marketing authorisation for Buprefarm was granted on 2018-11-14

The full PAR for Buprefarm can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Buprefarm, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-11.