LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Buripal
(buspirone, buspirone hydrochloride)

SE/H/2356/01-02/DC

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Tablet, 5 mg, 10 mg

This is a summary of the public assessment report (PAR) for Buripal. 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 Buripal and what is it used for?
The product is a 'generic medicine' (10 mg) and a 'hybrid medicine (5 mg). This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Buspar.

In this case, 'the hybrid medicine' means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

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

The product is a medicine that is used for the symptomatic treatment of anxiety states of clinically relevant severity with the following cardinal symptoms: anxiety, agitation, tension.

How does Buripal work?

Buspirone represents the first anxiolytic of the class of active substances known as azaspirones.

Buspirone works as an agonist on certain Serotonin receptors in the central nervous system.

How is Buripal used?

The pharmaceutical form is tablet for oral 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 Buripal have been shown in studies?

No additional studies were needed as the product is a generic medicine considered to be bioequivalent to the reference medicine, Buspar. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Buripal?

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 Buripal approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Buspar, 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 Buripal?

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.

Other information about Buripal

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

This summary was last updated in 2024-01