Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Buspirone Hydrochloride 5 mg Tablets
Buspirone Hydrochloride 10 mg Tablets.

buspirone hydrochloride

PL 16363/0687-0688

Milpharm Limited

LAY SUMMARY

Buspirone Hydrochloride 5 & 10 mg Tablets.
buspirone hydrochloride

This is a summary of the Public Assessment Report (PAR) for Buspirone Hydrochloride 5 & 10 mg 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 Buspirone Hydrochloride in this lay summary for ease of reading.

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

What is Buspirone Hydrochloride and what is it used for?
These products are generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised, called Buspar 10 mg tablets.

Buspirone Hydrochloride belongs to a group of medicines called anxiolytics.

Buspirone Hydrochloride may be used for the:
- short term management of anxiety disorders
- relief of symptoms of anxiety with or without symptoms of depression.

How does Buspirone Hydrochloride work?
These medicines work on the central nervous system, altering levels of chemicals in the brain.

How is Buspirone Hydrochloride used?
The pharmaceutical form of these medicines is a tablet and the route of administration is taken by mouth (for oral use)

Taking Buspirone Hydrochloride with food or drink
The patient should talk to their doctor before eating or drinking products containing grapefruit juice, whilst taking Buspirone Hydrochloride. The patient should *not* drink alcohol whilst taking Buspirone Hydrochloride.

The tablets should be swallowed with water, at the same time each day. Buspirone Hydrochloride should be taken consistently with or without food. However, the medicine is taken on the day one should be continued thereafter.

Doses:
Adults (including the elderly)
The starting dose is 5mg two to three times a day, which may be increased every two to three days. The usual dose you will be maintained on is 15mg to 30mg a day in divided doses up to a maximum dose of 45mg a day in divided doses.

Children: Not recommended.

If you have impaired liver or kidney function, your doctor may prescribe you a lower dose.

For further information on how Buspirone Hydrochloride 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 this medicine 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 Buspirone Hydrochloride have been shown in studies?
Buspirone Hydrochloride are generic medicines that fulfils criteria meaning that no additional studies are required. Buspirone Hydrochloride have been considered generic medicines of the reference medicines based on a comparison of their physical and chemical characteristics.

What are the possible side effects of Buspirone Hydrochloride?
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 medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Buspirone Hydrochloride are generic medicines, their benefits and possible side effects are considered to be the same as for the reference medicines.

Why was Buspirone Hydrochloride approved?
It was concluded that, Buspirone Hydrochloride has been shown to be comparable to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, 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 Buspirone Hydrochloride?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Buspirone Hydrochloride. The RMP details the important risks of Buspirone Hydrochloride, how these risks can be minimised, any uncertainties about Buspirone Hydrochloride (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Buspirone Hydrochloride.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Buspirone Hydrochloride are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Buspirone Hydrochloride
Marketing Authorisations for Buspirone Hydrochloride were granted in the United Kingdom (UK) on 13 May 2025.

The full PAR for Buspirone Hydrochloride follows this summary.

This summary was last updated in June 2025.

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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 applications for Buspirone Hydrochloride 5 & 10 mg Tablets. (PL 16363/0687-0688) could be approved.

The products are approved for the following indication(s):
Buspirone Hydrochloride is indicated for the short-term management of anxiety disorders and the relief of symptoms of anxiety with or without accompanying depression.

Mechanism of action
Buspirone Hydrochloride is an azaspirodecanedione. The exact mechanism of Buspirone Hydrochloride anxioselective action is not fully known. It does not act on benzodiazepine receptor sites and lacks sedative, anticonvulsant and muscle relaxant properties. From animal studies it is known to interact with serotonin, noradrenaline, acetylcholine and dopamine systems of the brain. Buspirone Hydrochloride enhances the activity of specific noradrenergic and dopaminergic pathways, whereas the activity of serotonin and acetylcholine are reduced.

These applications were approved under Regulation 51B of The Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended), as generic medicines of suitable originator medicinal products, Buspar 10 mg tablets that has been licensed for 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.

A biowaiver was submitted with these applications, which was accepted. No bioequivalence study was required and no new clinical studies were provided with these applications.

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.

Marketing Authorisations for Buspirone Hydrochloride were granted in the United Kingdom (UK) on 13 May 2025.

II QUALITY ASPECTS

II.1 Introduction

What Buspirone Hydrochloride contains

The active substance is Buspirone Hydrochloride

Buspirone Hydrochloride 5 mg Tablets
Each tablet contains 5 mg Buspirone Hydrochloride

Buspirone Hydrochloride 10 mg Tablets
Each tablet contains 10 mg Buspirone Hydrochloride

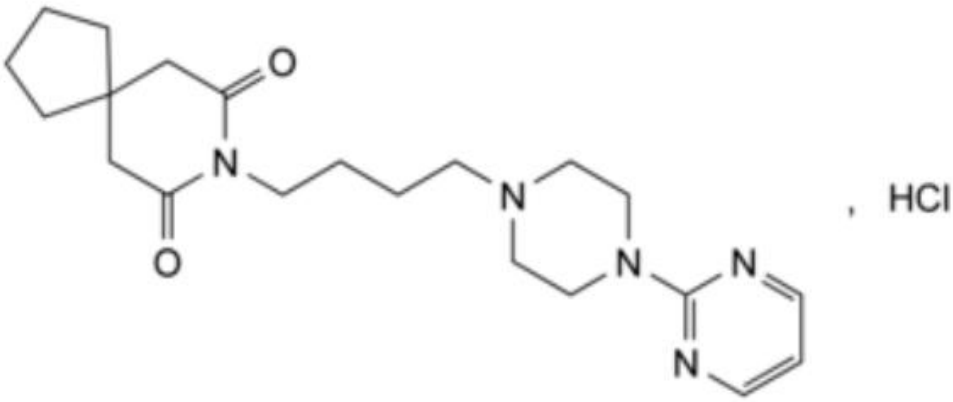
The other ingredients are:
Lactose monohydrate, cellulose, microcrystalline (grade -102), sodium starch glycolate (type – a), silica colloidal anhydrous, and magnesium stearate.

The contents of the pack
Buspirone Hydrochloride 5 mg Tablets are packaged in blister strips placed in cartons of 30 tablets.

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: Buspirone hydrochloride
Chemical Name: 8-[4-[4-(Pyrimidin-2-yl)piperazin-1-yl]butyl]-8-azaspiro[4.5]decane-7,9-dione hydrochloride.
Molecular Formula: $C_{21}H_{32}ClN_5O_2$
Chemical Structure:



Molecular Weight: 422.0
Appearance: White or almost white, crystalline powder.
Solubility: Freely soluble in water and in methanol, practically insoluble in acetone.

Buspirone hydrochloride 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 PRODUCTS

Pharmaceutical development

A satisfactory account of the pharmaceutical development was provided.

Comparative *in vitro* dissolution and impurity profiles were provided for the proposed and reference products.

All excipients comply with either their respective European/national monographs, or suitable in-house specification. Satisfactory Certificates of Analysis were provided for all excipients.

With the exception of lactose monohydrate, no excipients of animal or human origin are used in the final products.

The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.>

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 3 years, with the storage condition, store in the original package in order to protect from light, is acceptable.

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The grant of marketing authorisations was recommended.

III NON-CLINICAL ASPECTS

III.1 Introduction
As the pharmacodynamic, pharmacokinetic and toxicological properties of buspirone hydrochloride 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 was provided for non-submission of an Environmental Risk Assessment. As the applications are for generic version(s) of an 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 was recommended.

IV CLINICAL ASPECTS

IV.1 Introduction
The clinical pharmacology, efficacy and safety of buspirone hydrochloride are well-known. According to the regulatory requirements, the applicant has provided suitable biowaiver and a bioequivalence study is not required for these products. An overview based on a literature review is, thus, satisfactory.

IV. 2 Pharmacokinetics
No new pharmacokinetic data were submitted for these applications and none were required.

IV.3 Pharmacodynamics
No new pharmacodynamic data were 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
No new safety data were submitted with these applications and none were required. The safety profile for these products is considered to be the same as Buspar 10 mg tablets.

IV.6 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.

IV.7 Discussion on the clinical aspects

The grant of marketing authorisations was recommended for these applications.

V USER CONSULTATION

A grey-scale mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

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 buspirone hydrochloride 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), Patient Information Leaflet (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 PILs for these products are available on the MHRA website.

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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**