NEWBURY

EU RISK MANAGEMENT PLAN FOR BUSPIRON

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Buspirone Newbury (Buspirone)

This is a summary of the risk management plan (RMP) for Buspirone Newbury. The RMP details important risks of Buspirone Newbury, how these risks can be minimised, and how more information will be obtained about Buspirone Newbury 's risks and uncertainties (missing information).

Buspirone Newbury 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Buspirone Newbury should be used.

I. The medicine and what it is used for

Buspirone Newbury is authorised for indication outline for the symptomatic treatment of anxiety states of clinically relevant severity with the following cardinal symptoms: anxiety, agitation, tension. (see SmPC for the full indication).

It contains Buspirone hydrochloride as the active substance and it is given by oral.

Il. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Buspirone Newbury together with measures to minimise such risks and the proposed studies for learning more about Buspirone Newbury's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.

Important advice on the medicine's packaging.

The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.

The medicine's legal status - the way a medicine is supplied to the patient (e.g., with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

Il.A List of important risks and missing information

List of im ortant risks and missin information	
1m ortant identified risks	None
List of im ortant risks and missin information	
1m ortant otential risks	None
Missin information	None

Il.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Buspiron.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Buspiron.