

Summary of the Risk Management Plan for RXULTI

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

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

This summary of the RMP for RXULTI should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR). Important new concerns or changes to the current ones will be included in updates of RXULTI's RMP.

I: The Medicine and What it is Used for

RXULTI is authorised for the treatment of schizophrenia in adult patients (see SmPC for the full indication). It contains brexpiprazole as the active substance and it is given orally.

Further information about the evaluation of RXULTI's benefits can be found in RXULTI's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

<https://www.ema.europa.eu/en/medicines/human/EPAR/rxulti>

II: Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of RXULTI together with measures to minimise such risks and the proposed studies for learning more about RXULTI'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, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of RXULTI is not yet available, it is listed under 'missing information' below.

II.A: List of Important Risks and Missing Information

Important risks of RXULTI are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of RXULTI. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine).

Table 1: List of Important Risks and Missing Information	
Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• Use in pregnancy and lactation • Use in elderly (age > 65).

II.B: Summary of Important Risks and Missing Information

Table 2: Use in Pregnancy and Lactation	
Risk minimisation measures	Routine risk minimisation measures: Routine risk communication: • SmPC Sections 4.6, 5.3 • PL Section 2 Legal status: Prescription only medicine Additional risk minimisation measures: No additional risk minimisation measures.
Additional pharmacovigilance activities	Data collection from participation in the NPRAA

Table 3: Use in Elderly (> 65)	
Risk minimisation measures	Routine risk minimisation measures: Routine risk communication: • SmPC Sections 4.2, 4.4 • PL Section 2 Legal status: Prescription only medicine Additional risk minimisation measures: No additional risk minimisation measures.

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 RXULTI.

II.C.2 Other Studies in Post-authorisation Development Plan

NPRAA

Purpose of the study: To systematically and prospectively monitor pregnancy outcomes in individuals using atypical antipsychotics.