Summary of risk management plan for Ximluci (Ranibizumab)

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

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

This summary of the RMP for Ximluci 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 Ximluci's RMP.

I. The medicine and what it is used for

Ximluci is indicated in adults for the treatment of:

- neovascular (wet) age-related macular degeneration (AMD)
- visual impairment due to diabetic macular oedema (DME)
- proliferative diabetic retinopathy (PDR)
- visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)
- visual impairment due to choroidal neovascularisation (CNV)

(see SmPC for the full indication). It contains ranibizumab as the active substance and it is a solution for injection and must be administered by a qualified ophthalmologist experienced in intravitreal injections.

Further information about the evaluation of Ximluci’s benefits can be found in Ximluci’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/ximluci.

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

Important risks of Ximluci, together with measures to minimise such risks and the proposed studies for learning more about Ximluci'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 the case of Ximluci, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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*.

II.A List of important risks and missing information

Important risks of Ximluci are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Ximluci. 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 6-1: List of important risks and missing information

List of important risks and missing information	
Important identified risks	• Infectious endophthalmitis • Intraocular inflammation • Retinal detachment and retinal tear • Intraocular pressure increase
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Table 6-2: Summary of important risks

Infectious endophthalmitis **Important identified risk**	
Risk minimisation measures	**Routine risk minimisation measures** SmPC Sections 4.2, 4.3, 4.4, 4.8 and 6.6 **Additional risk minimisation measures** (for indications of AMD, CNV, DME, RVO and PDR): Educational plan for adult patients

Intraocular inflammation **Important identified risk**	
Risk minimisation measures	**Routine risk minimisation measures** SmPC Sections 4.3 and 4.4 **Additional risk minimisation measures** (for indications of AMD, CNV, DME, RVO and PDR): Educational plan for adult patients

Retinal detachment and retinal tear **Important identified risk**	
Risk minimisation measures	**Routine risk minimisation measures** SmPC Sections 4.4 and 4.8 **Additional risk minimisation measures** (for indications of AMD, CNV, DME, RVO and PDR): Educational plan for adult patients

Intraocular pressure increase **Important identified risk**	
Risk minimisation measures	**Routine risk minimisation measures** SmPC Sections 4.4, 4.8 and 4.9 **Additional risk minimisation measures** (for indications of AMD, CNV, DME, RVO and PDR): Educational plan for adult patients

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 Ximluci.

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

There are no studies required for Ximluci.