Summary of Risk Management Plan (RMP)

Aloxi (palonosetronum)

Aloxi, solution for injection

Aloxi 500 micrograms, soft capsules

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Based on EU RMP version 7.1

Medius AG, Switzerland

Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Aloxi is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Aloxi, solution for injection and Aloxi 500 micrograms, soft capsules in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. Medius AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Aloxi.

Summary of the risk management plan

A separate RMP summary is provided for each product in the RMP. The first summary refers to Aloxi 250 micrograms solution for injection and the second summary to Aloxi 500 micrograms soft capsules.

Summary of risk management plan for Aloxi 250 micrograms solution for injection

This is a summary of the risk management plan (RMP) for **Aloxi 250 micrograms solution for injection**. The RMP details important risks of Aloxi 250 micrograms solution for injection, how these risks can be minimised, and how more information will be obtained about Aloxi 250 micrograms solution for injection risks and uncertainties (missing information).

Aloxi 250 micrograms solution for injection summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Aloxi 250 micrograms solution for injection should be used. This summary of the RMP for Aloxi 250 micrograms solution for injection 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 Aloxi 250 micrograms solution for injection RMP.

I. The medicine and what it is used for

Aloxi 250 micrograms solution for injection is indicated in adults for the:

- Prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy,
- Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Aloxi 250 micrograms solution for injection is indicated in paediatric patients 1 month of age and older for the:

- Prevention of acute nausea and vomiting associated with highly emetogenic cancer chemotherapy and prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy.

Further information about the evaluation of Aloxi 250 micrograms solution for injection benefits can be found in Aloxi 250 micrograms solution for injection EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Aloxi 250 micrograms solution for injection, together with measures to minimize such 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 public (e.g., with or without prescription) can help to minimises 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/PBRER 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 Aloxi 250 micrograms solution for injection is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Aloxi 250 micrograms solution for injection are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks of Aloxi 250 micrograms solution for injection can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Aloxi 250 micrograms solution for injection. Potential risks are concerns for which an association with the use of this medicine is possible based on some preliminary data, but this association has not been fully proven 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	Torsade de pointes due to QT/QTC prolongation Serotonin Syndrome
Missing information	Effect in children aged less than 1 month (potential off-label use for CINV prevention)

II.B Summary of important risks

Important potential risk: Torsade de pointes due to QT/QTC prolongation	
Evidence for linking the risk to the medicine	Clinical studies have not showed relevant effects on the prolongation of the QT/QTc interval. Nevertheless, since cancer patients are a vulnerable population receiving potentially cardiotoxic antineoplastic agents, or with medical history remarkable for cardiac disease on treatment with antiarrhythmics, or may carry electrolytes imbalance, it is prudent to consider Torsade de pointes due to QT/QTc prolongation an important potential risk.
Risk factors and risk groups	Risk factors include drug interaction with concomitant medication such as anthracyclines, cyclophosphamide or antiarrythmic drugs, preexisting cardiac disease (e.g., cardiac ischaemia, cardiomyopathies, congenital long QT syndrome, rhythm disturbances), hypertension, atherosclerosis, malnutrition or electrolytes abnormalities (including that caused by diuretics and dehydration), or treatment with drugs known to prolong QT interval, hypothyroidism, hypoglycaemia and a wide range of chemotherapy agents. Female sex and older age are also associated with longer QT intervals.
Risk minimisation measures	• Routine risk communication: SmPC sections 4.4 and 4.8, PL sections 2 and 4. • Routine risk minimisation activities recommending specific clinical measures to address the risk: advice is given for monitoring of patients with conditions leading to QT prolongation in SmPC section 4.4 and inform patients on the importance of this medical condition in PL section 2 and of possible undesirable effects in PL section 4.

	• Other routine risk minimisation measures beyond the Product Information: none • Legal status: prescription only medicine.

Important potential risk: Serotonin syndrome	
Evidence for linking the risk to the medicine	The occurrence of Serotonin Syndrome (SS) has been considered as a potential class effect of the anti-emetics belonging to the class of the 5- HT3 RAs. Serotonin syndrome is a potentially life-threatening drug reaction that may occur following therapeutic drug use. The excess serotonin activity produces a spectrum of specific symptoms including cognitive, autonomic, and somatic effects, which can be of variable intensity.
Risk factors and risk groups	Patients on treatment with antidepressant, or with triptanes for migraine or cluster headaches. Patients on therapy with anti-parkinson agents, or antidepressants for fibromyalgia or chronic fatigue. Use of illicit drugs (ecstasy, LSD), or herbal and nutritional supplements (St.John's wort, panag ginseng) may increase the risk. Susceptibility to serotonin syndrome may be also conferred by patient's factors, such as the capacity to metabolize certain drugs.
Risk minimisation measures	• Routine risk communication: none. • Routine risk minimisation activities recommending specific clinical measures to address the risk: specific information on the serotonin syndrome when palonosetron is administered with other serotoninergic agents is included in SmPC sections 4.4 and 4.5.

	• Specific information on the SS when palonosetron is administered with other serotoninergic agents and how to make aware patients of the importance of informing healthcare professionals of the use of other medicinal products in PL section 2. • Other routine risk minimisation measures beyond the Product Information: none • Legal status: Prescription only medicine

Missing information: Effects in children aged less than 1 month	

Risk minimisation measures	• Routine risk minimisation measures:
	  • SmPC Sections 4.2, 4.6 and 5.1
	  • PL sections 1, 3 and 4 where advice to not use the product in children below 1 month due to lack of safety and efficacy data is reported
	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 Aloxi 250 micrograms solution for injection.

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

There are no studies required for Aloxi 250 micrograms solution for injection.

Summary of risk management plan for Aloxi 500 micrograms soft capsules

This is a summary of the risk management plan (RMP) for **Aloxi 500 micrograms soft capsules.** The RMP details important risks of Aloxi 500 micrograms soft capsules, how these risks can be minimised, and how more information will be obtained about Aloxi 500 micrograms soft capsules risks and uncertainties (missing information). Aloxi 500 micrograms soft capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Aloxi 500 micrograms soft capsules should be used. This summary of the RMP for Aloxi 500 micrograms soft capsules 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 Aloxi 500 micrograms soft capsules RMP.

I. The medicine and what it is used for

Aloxi 500 micrograms soft capsules is indicated in adults for the:

- Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.

Aloxi 500 micrograms soft capsules is indicated in adults only because the safety and efficacy in children have not been established.

Further information about the evaluation of benefits of Aloxi 500 micrograms soft capsulescan be found in Aloxi 500 micrograms soft capsules EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Aloxi 500 micrograms soft capsules together with measures to minimise such 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 public (e.g., with or without prescription) can help to minimises 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/PBRER 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 Aloxi 500 micrograms soft capsules is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Aloxi 500 micrograms soft capsules are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. Important risks of Aloxi 500 micrograms soft capsules can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Aloxi 500 micrograms soft capsules. Potential risks are concerns for which an association with the use of this medicine is possible based on some preliminary 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.

List of important risks and missing information	
Important identified risks	None
Important potential risks	Torsade de pointes due to QT/QTC prolongation Serotonin syndrome
Missing information	None

II.B Summary of important risks

Important potential risk: Torsade de pointes due to QT/QTC prolongation	
Evidence for linking the risk to the medicine	Clinical studies have not showed relevant effects on the prolongation of the QT/QTc interval. Nevertheless, since cancer patients are a vulnerable population receiving potentially cardiotoxic antineoplastic agents, or with medical history remarkable for cardiac disease on treatment with antiarrhythmics, or may carry electrolytes imbalance, it is prudent to consider Torsade de pointes due to QT/QTc prolongation an important potential risk.

Risk factors and risk groups	Risk factors include drug interaction with concomitant medication such as anthracyclines, cyclophosphamide or antiarrythmic drugs, preexisting cardiac disease (e.g., cardiac ischaemia, cardiomyopathies, congenital long QT syndrome, rhythm disturbances), hypertension, atherosclerosis, malnutrition or electrolytes abnormalities (including that caused by diuretics and dehydration), or treatment with drugs known to prolong QT interval, hypothyroidism, hypoglycaemia and a wide range of chemotherapy agents. Female sex and older age are also associated with longer QT intervals.
Risk minimisation measures	• Routine risk communication: SmPC sections 4.4 and 4.8, PL sections 2 and 4. • Routine risk minimisation activities recommending specific clinical measures to address the risk: advice is given for monitoring of patients with conditions leading to QT prolongation in SmPC section 4.4 and inform patients on the importance of this medical condition in PL section 2 and of possible undesirable effects in PL section 4. • Other routine risk minimisation measures beyond the Product Information: none • Legal status: prescription only medicine.
Important potential risk: Serotonin syndrome	
Evidence for linking the risk to the medicine	The occurrence of Serotonin Syndrome (SS) has been considered as a potential class effect of the anti-emetics belonging to the class of the 5- HT_3 RAs. SS is a potentially life-threatening drug reaction that may occur following therapeutic drug use. The excess serotonin activity produces a spectrum of specific symptoms including

	cognitive, autonomic, and somatic effects, which can be of variable intensity.
Risk factors and risk groups	Patients on treatment with antidepressant, or with triptanes for migraine or cluster headaches. Patients on therapy with anti-parkinson agents, or antidepressants for fibromyalgia or chronic fatigue. Use of illicit drugs (ecstasy, LSD), or herbal and nutritional supplements (St. John's wort, panag ginseng) may increase the risk. Susceptibility to serotonin syndrome may be also conferred by patient's factors, such as the capacity to metabolize certain drugs.
Risk minimisation measures	• Routine risk communication: none. • Routine risk minimisation activities recommending specific clinical measures to address the risk: specific information on the serotonin syndrome when palonosetron is administered with other serotoninergic agents is included in SmPC sections 4.4 and 4.5. • Specific information on the SS when palonosetron is administered with other serotoninergic agents and how to make aware patients of the importance of informing healthcare professionals of the use of other medicinal products in PL section 2. • Other routine risk minimisation measures beyond the Product Information: none • Legal status: Prescription only medicine

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 Aloxi 500 micrograms soft capsules.

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

There are no studies required for Aloxi 500 micrograms soft capsules.