Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 259 -260 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.124
Short communication

Risk management of AMINAL concentrates for haemodialysis

Ajra Sinanova*, Lora Atanasovska, Marija Davceva Jovanoska, Olivera Paneva

Pharmaceutical Chemical Cosmetic Industry ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia

Introduction

Risk management is a crucial process to ensure patient safety, product quality and performance throughout the entire life cycle of the medical device. AMINAL concentrates for bicarbonate haemodialysis are intended for the treatment of patients with kidney insufficiency or failure, where different types of risks may impact patient safety and therefore need to be effectively managed.

The objective of this study is to present a comprehensive overview of the risk management process for AMINAL concentrates for haemodialysis.

Risk management planning

The risk management process for AMINAL concentrates for haemodialysis has a multidisciplinary approach involving all relevant departments across the lifecycle of the device, including Research and Development, Production, Quality Control, Warehouses, Sales, and Regulatory Affairs. The process is coordinated by Quality Assurance and starts with the establishment of a Risk Management Plan, which defines the framework for all subsequent risk management activities.

The Risk Management Plan outlines team responsibilities, conditions for reviewing and updating the risk management file, criteria for risk acceptability, the approach for evaluation of overall residual risk, verification of implementation and effectiveness of risk control measures, and activities for the collection and review of production and post-production information.

Risk assessment and risk control

Risk assessment encompasses risk analysis and risk evaluation.

Risk analysis includes the identification of potential hazards across the medical device lifecycle and risk estimation for each identified risk. Risk estimation is performed using FMEA, where severity, frequency, and detectability are assigned numerical values, and their product defines the Risk Priority Number (RPN). Based on the RPN, risks are classified as low, medium, high, and critical.

Risk evaluation is performed by comparing the estimated risks with the criteria for risk acceptability; for AMINAL concentrates for haemodialysis that are placed on the market, all the risks that are classified as low and medium are considered acceptable.

Risk control includes defining and implementing activities to reduce unacceptable risks or monitoring of acceptable risks to maintain them at an acceptable level. It also includes residual risk evaluation, benefit–risk analysis (when applicable), and review of risks arising from control measures.

For AMINAL concentrates for haemodialysis, there is a total of 56 risks identified, of which 11 risks

*asinanova@alkaloid.com.mk

refer only to AMINAL SET and 1 risk refers only to the AMINAL CITRATE group of products. From 56 risks in total, 38 of them are classified as low risks, and 18 are classified as medium risks. According to defined criteria, all identified risks are acceptable and appropriate activities for monitoring are in place.

Evaluation of overall residual risk

The evaluation of the overall residual risk for AMINAL concentrates for haemodialysis is based on benefit–risk analysis. All previously evaluated individual residual risks are grouped into five categories depending on the type of risk: environmental risks, physical risks, chemical risks, biological risks and risks in use. Descriptive benefit–risk analyses are performed for each category. The results from these analyses demonstrate that the residual risks do not exceed the intended benefits of the medical device, which confirms that the overall residual risk is acceptable.

After confirmation that the overall residual risk is acceptable, the team defines which risks will be disclosed to the user. For AMINAL concentrates for haemodialysis, most of the residual risks in use are disclosed through information provided in the instructions for use (IFU) and on the label.

Risk management review

Risk management review is initially performed after implementation of all risk control measures and prior to placing the medical device on the market. After the device is placed on the market, risk management review is regularly performed based on production and post-production information and the results are documented in the Risk Management Report. The Risk Management Report confirms that the Risk Management Plan is properly implemented, that the overall residual risk is acceptable, and that appropriate methods for collection and review of production and post-production information are in place.

Production and post-production activities

Evaluation of production and post-production activities is performed at least once a year by the risk management team.

First, information collection is carried out through defined processes: change control, non-conformities, supplier assessment, monitoring in production, validation, storage and distribution for production data, and complaints, recalls, post-market surveillance (PMS), clinical evaluation and medical device vigilance for post-production data.

Second, the collected information is reviewed for its impact on the safety, quality and performance of the medical device.

Third, if a hazard affecting identified risks or a new risk arises, re-evaluation is performed and activities are defined to monitor, control and reduce the risks.

Conclusion

The risk management process for AMINAL concentrates for haemodialysis is appropriately implemented and ensures systematic identification, assessment, control and monitoring of risks throughout the lifecycle of the medical device based on current regulatory requirements.

All identified risks are reduced to acceptable levels, with effective risk control measures and risk monitoring activities implemented within the quality management system. The overall residual risk is considered acceptable, and the benefit–risk ratio remains in favor of the benefits of the medical device.

Continuous collection and review of production and post-production information ensures maintenance of product quality, safety and performance and provides a basis for continuous improvement of the risk management process.

References

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, 2017. Official Journal of the European Union.

ISO 14971, 2019. Medical devices – Application of risk management to medical devices. International Organization for Standardization.

ISO/TR 24971, 2020. Medical devices – Guidance on the application of ISO 14971. International Organization for Standardization.