VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

PhyBag 9 mg/ml is indicated for diagnostic use only. It is indicated for flushing well-suited contrast agents into vessels and it has no mechanism of action in the human body. Contrast agents are used in Computerised Tomography (CT) scanning procedures in order to identify and/or visualise a disease condition; the diagnosis is made by using the contrast, while PhyBag 9 mg/ml only supports the procedure in a physical manner rather than in a pharmacological way.

VI.2.2 Summary of treatment benefits

Saline flushing of contrast agents optimises the protocols of various CT examinations. Nowadays many diagnostic protocols exist where the timely arrival of the contrast in the region of interest of the body is essential for the diagnostic quality.

With the saline flush immediately following the contrast agent administration, the contrast agent is removed from the tubing and from peripheral vessels which allows the timely arrival of the contrast when the CT scan is started. Moreover, with this approach, the amount of contrast agent in the tubing and peripheral vessels is fully available for scanning which reduces the overall amount of contrast needed. Together with appropriate power injectors, standardised injection protocols are possible and the benefits from such protocols are a reduction of the contrast agent dose, which increase the overall safety of the procedures and an overall improvement of the diagnostic quality. Sterility is improved compared to the filling of an empty syringe with saline from a bottle.

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VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known (Including reason why it is considered an identified risk)
Extravasation	Generally, most extravasation injuries with injectable drugs are minor and resolve spontaneously in 2–4 days. More severe injuries include skin ulceration, tissue necrosis and compartment syndrome, depending of the nature and physico-chemical properties of the injected drug. However, PhyBag 9 mg/ml is a saline solution iso-osmolar to plasma and the injected volume is limited so that extravasation and negative consequences seems unlikely.
Fluid overload	Fluid overload of large volume of saline solution used for fluid and electrolyte replacement may have serious consequences in patients with cardiac, renal or electrolyte imbalance. However, due to the limited volume of PhyBag 9 mg/ml administered as a saline flush during imaging procedure, fluid overload is not expected and its impact on patient's preexisting conditions would be limited.
Air embolism	Most cases of air embolism are asymptomatic and undetected. Administration of saline flush through a peripheral vein during a few seconds is unlikely to cause introduction of large volume of air.
Infectious complications	Infection at the injection site is a known side effect of drugs and fluids. Infection complication may be localized to tissues around the catheter insertion site and the catheter itself. However, for saline flush administration during CT procedure, the peripheral catheter is left in place only for the time required for the CT.

Important potential risks

None

Missing information

None

VI.2.5 Summary of additional risk minimisation measures by safety concern

PhyBag 9 mg/ml has a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimizing them. An abbreviated version of this SmPC in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisations measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1	April 2015	Not applicable	Creation of RMP in context of MA Application for a new indication