FUTUREHEALTH

Summary of EU Risk Management Plan (RMP)

Name of the medicinal product:	Hexvix, powder and solvent for intravesical solution
Active substance:	Hexaminolevulinate Hydrochloride
Version number of the current RMP:	3.0
Name of the marketing authorisation holder:	Future Health Pharma GmbH
Date of RMP:	24.01.2019

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 “Hexvix” 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 “Hexvix” in Switzerland is the “Arzneimittelinformation/ Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. “Future Health Pharma GmbH” is fully responsible for the accuracy and correctness of the content of the published summary RMP of “Hexvix”.

SUMMARY OF THE RISK MANAGEMENT PLAN FOR HEXVIX (HEXAMINOLEVULINATE)

This is a summary of the risk management plan (RMP) for Hexvix. The RMP details important risks of Hexvix and how these risks can be minimized.

The Summary of Product Characteristics (SmPC) and package leaflet for Hexvix give essential information to healthcare professionals and patients on how Hexvix should be used.

Important new concerns or changes to the current ones will be included in updates of this RMP.

I. The Medicine and What it is Used for

Hexvix is used in patients with known or suspected bladder cancer during cystoscopy (a procedure where a thin telescope called a cystoscope is passed up the urethra and into the bladder) to improve the detection of cancer. The active ingredient is hexaminolevulinate hydrochloride (HAL).

II. Risks Associated with the Medicine and Activities to Minimise or further Characterise the Risks

Important risks of Hexvix, together with measures to minimize such risks, are outlined below. Measures to minimize 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, respectively;
- important advice on the medicine's packaging;
- the authorized 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 minimize its risks.

Together, these measures constitute routine risk minimization measures. In the case of Hexvix, these measures are considered sufficient. No additional risk minimization measures are in place.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including periodic safety update report 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 Hexvix is not available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Hexvix are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely used. 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 Hexvix. 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.

Table 11: Summary of Safety Concerns	
Important identified risks	• Anaphylactoid reactions/hypersensitivity
Important potential risks	• None
Missing information	• None

II.B Summary of Important Risks

Table 11: Important identified risk: Anaphylactoid reactions/hypersensitivity	
Evidence for linking the risk to the medicine	Non-serious hypersensitivity reactions were uncommonly reported m clinical trials. Isolated post-marketing reports of serious anaphylactoid reactions, including anaphylactoid shock have been received. In each of these cases, possible alternative explanations were reported, or case documentation was insufficient to rule out alternative causes. All patients reportedly had recovered or were recovering at the time of the report. In general, although anaphylactoid reactions of any cause are potentially life-threatening, outcome is usually favourable if the patient is managed appropriately. Hexvix is always administered in a hospital or medical office setting where advanced life support facilities should be readily available.
Risk factors and risk groups	No specific risk groups or risk factors for hypersensitivity reactions to Hexvix are known. For drug hypersensitivity reactions in general the most important risk factor is a previous reaction to the same or a related compound
Risk minimization measures	• Use of Hexvix is contraindicated in patients with known hypersensitivity to the active ingredient or excipients. • The package leaflet and SmPC include a warning about the possibility of hypersensitivity including serious anaphylactic/anaphylactoid reactions and requires that advanced life support facilities should be readily available. • The package leaflet and SmPC list hypersensitivity, including anaphylactoid shock, as undesirable effects. • Hexvix 1s prescription-only medicine, administered by healthcare professionals in hospital or medical office setting.

II.C Post-Authorisation Development Plan

There are no studies which are conditions of the marketing authorisation or specific obligation of Hexvix. No other studies are required for Hexvix as part of the post-authorisation development plan.