Part VI: Summary of the risk management plan

Summary of risk management plan for MYDRANE (tropicamide, phenylephrine, lidocaine)

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

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

I. The medicine and what it is used for

MYDRANE is authorised for cataract surgery to obtain mydriasis and intraocular anaesthesia during the surgical procedure. It contains tropicamide, phenylephrine, lidocaine as active substances and it is given by intracameral route.

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

Important risks of MYDRANE together with measures to minimise such risk and the proposed studies for learning more about MYDRANE's risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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 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.

If important information that may affect the safe use of MYDRANE is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of MYDRANE 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 MYDRANE. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	Corneal endothelial toxicity
Missing information	None

II.B Summary of important risks

Important potential risk – Corneal endothelial toxicity	
Evidence for linking the risk to the medicine	During clinical studies, corneal endothelial toxicity was not reported at the recommended dose. However, increased endothelial cell loss was observed when patients received a second injection.
Risk factors and risk groups	Risk groups included patients with endothelial cell count <2000 cell/mm², corneal dystrophy, history of traumatism, acute glaucoma, anterior or posterior segments surgery, advanced age, hard nucleus density. Risk factors included cataract surgery (i.e. high ultrasound energy, long phacoemulsification time, phacoemulsification technique), and product dose (i.e. important number and/or volume of injections).
Risk minimisation measures	<u>Routine risk minimisation measures:</u> • SmPC section 4.4, 4.9 • PL section 3 • Prescription only medicine • Restricted use to ophthalmic surgeons

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 MYDRANE.

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

There are no studies required for MYDRANE.

Part VII: Annexes

Table of contents

Annex 1 – EudraVigilance Interface

Annex 1 is not required to be submitted in eCTD; the electronic file is submitted in accordance to GVP Module V.

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable

Annex 7 - Other supporting data (including referenced material)

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Annex 8 – Summary of changes to the risk management plan over time

Version	Approval date Procedure	Change
1.0	**Approval date:** Not applicable **Procedure number:** SE/H/1351/001/DC	RMP creation
2.0	**Approval date:** Not applicable **Procedure number:** DK/H/2439/001/DC	Modification of decentralised procedure number from SE/H/1351/001/DC to DK/H/2439/001/DC
2.1	**Approval date:** Not applicable **Procedure number:** DK/H/2439/001/DC	Update in accordance with the D106 assessment report
2.2	**Approval date:** Not applicable **Procedure number:** DK/H/2439/001/DC	Update in accordance with the D160 assessment report
2.3	**Approval date:** 02-Jul-2015 **Procedure number:** DK/H/2439/001/DC	Update following the approval of the SmPC
3.0	**Approval date:** Not applicable **Procedure number:** DK/H/2439/001/R/01	Update according to the new European template (GVP Module V, Rev 2). • The important identified risk "Hypersensitivity reaction" was reclassified from safety concern to non-important risk. • The important potential risk "Phenylephrine systemic effect" was reclassified from safety concern to non-important risk. • The important potential risk "Lidocaine systemic effect" was reclassified from safety concern to non-important risk.

		• The important potential risk "Tropicamide systemic effect" was reclassified from safety concern to non-important risk.
4.0	**Approval date:** Not applicable **Procedure number:** DK/H/2439/001/R/01	Update following the RMP assessment during the marketing authorisation renewal procedure. The missing information "Use in pregnant or breastfeeding women", "Use in paediatrics", "Use in patients with non-satisfactory pupil dilation controlled during the pre-operative visit", "Use in insulin-dependent or uncontrolled diabetic patients", "Use in patients with corneal disease", "Use in patients with history of uveitis" were removed from the list of safety concerns.