# Summary of the Risk Management Plan (RMP)

for

# Dificlir™ (fidaxomicin)

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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 Dificlir 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 Dificlir in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Tillotts Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Dificlir.

# I. THE MEDICINE AND WHAT IT IS USED FOR

Dificlir (fidaxomicin) is authorized for the treatment of *Clostridioide difficile* infection also known as *Clostridioide difficile*-associated diarrhea in adult and pediatric patients. Dificlir contains fidaxomicin as the active substance and is available as film-coated tablet or granules for oral suspension for oral use.

Further information about the evaluation of Dificlir's benefits can be found in Dificlir's European Public Assessment Report, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/dificlir

# II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Dificlir, together with measures to minimize such risks and the proposed studies, if any for learning more about Dificlir's 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;
- 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 addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Dificlir is not yet available, it is listed under 'missing information' below.

## II.A List of Important Risks and Missing Information

Important risks of Dificlir 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 can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Dificlir. 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** | |
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| Important identified risks | None |
| Important potential risks | None |
| Missing information | None |

## II.B Summary of Important Risks

None.

## II.C Post-authorization Development Plan

### II.C.1 Studies which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Dificlir.

### II.C.2 Other Studies in Postauthorization Development Plan

There are no studies required for Dificlir.