RMP Summary

RMP Version 6.0 – 02-Dec-2021

Accofil, Fertigspritzen

ZL-Nr.: 66715

Filgrastim

Accord Healthcare AG
4103 Bottmingen

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

Part VI: Summary of the risk management plan

Summary of risk management plan for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe (filgrastim)

This is a summary of the risk management plan (RMP) for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe. The RMP details important risks of for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's risks and uncertainties (missing information).

Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe should be used.

This summary of the RMP for Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's RMP.

I. The medicine and what it is used for

Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe is authorised for reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes) (see SmPC for the full indication). It contains filgrastim as the active substance and it is given by subcutaneous or intravenous route.

Further information about the evaluation of Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's benefits can be found in Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. Link to the EPAR summary landing page

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

Important risks of Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe, together with measures to minimise such risks and the proposed studies for learning more about Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe's risks, are outlined below.

Measures to minimise 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 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 and signal management activity, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe 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 Accofil 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe. 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);

Important identified risks	· None
Important potential risks	· None
Missing information	· None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which conditions of the marketing authorization or specific obligation of 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe.

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

There are no studies required for 30 MU/0.5 ml, 48 MU/0.5 ml, 12 MU/0.2 ml and 70 MU/0.73 ml solution for injection or infusion in pre-filled syringe and Grastofil 30 MU/0.5 ml and 48 MU/0.5 ml solution for injection/infusion in pre-filled syringe as post-authorisation development plan.