Summary of the risk management plan for Lagevrio (molnupiravir)

Introduction

This document is a summary of the risk management plan (RMP) for Lagevrio (molnupiravir). The RMP was created by the drug manufacturer and is submitted to medicine regulators as part of the approval and safety monitoring processes.

The RMP details important risks of Lagevrio, how these risks can be minimised, and how more information will be obtained about Lagevrio's risks and uncertainties (missing information). Important new changes or changes to the current ones will be included in updates of the RMP by the drug manufacturer.

The Lagevrio data sheet and Consumer Medicine Information (CMI) give essential information for healthcare professionals and patients on how to use this medicine.

RMP Definitions

Important risks

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

Important risks are classified as identified or potential.

- Identified risks are concerns for which there is sufficient proof of a link with the use of the medicine.
- 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

Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

Activities to minimise or further characterise identified risks

Measures to minimise the identified risks for medicinal products may include:

- specific information for healthcare professionals and patients, such as warnings, precautions and advice on correct use, in the data sheet, consumer medicine information and package leaflet
- 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 (eg, 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 events is collected continuously by the company and regularly analysed, so that immediate action can be taken by the company as necessary. These measures constitute *routine pharmacovigilance activities*.

Other non-routine measures to further characterise the risks include safety and efficacy studies. The studies may be in particular risk groups or for particular safety concerns. They may also be a condition of the medicine's approval. These measures constitute *additional pharmacovigilance activities*.

Lagevrio (molnupiravir) RMP

The medicine and what it is used for

Lagevrio is an oral antiviral medicine used for the treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults aged 18 years and older who are at increased risk of progressing to severe COVID-19, hospitalisation, or death.

Lagevrio contains the active substance: molnupiravir.

Important risks, missing information and additional pharmacovigilance activities

The tables below summarise the risks for Lagevrio, as described in the RMP.

- Table 1 is a list of the important risks (identified and potential) and missing information.
- Tables 2 and 3 provide risk minimisation measures and a list of additional pharmacovigilance activities.

Table 1: List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	Safety in pregnancy Safety in lactation

Table 2: Missing information: Safety in pregnancy

Risk minimisation measures	Sections 4.6 and 5.3 of the data sheet Consumer medicine information leaflet
Additional pharmacovigilance activities	None

Table 3: Missing information: Safety in lactation

Risk minimisation measures	Section 4.6 of the data sheet Consumer medicine information leaflet
Additional pharmacovigilance activities	None