Part VI: Summary of the risk management plan

Summary of risk management plan for Ezetimib(e) Vivanta/ MSN 10mg tablets (Ezetimibe).

This is a summary of the risk management plan (RMP) for Ezetimib(e) Vivanta/ MSN 10mg tablets. The RMP details important risks of Ezetimibe, how these risks can be minimised, and how more information will be obtained about Ezetimibe´s risks and uncertainties (missing information).

Ezetimibe´s summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how the tablets should be used.

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

I. The medicine and what it is used for

Ezetimib(e) Vivanta/ MSN 10mg tablets contain ezetimibe as the active substance and are given by oral route of administration. The tablets are authorized for the following indications:

Primary Hypercholesterolaemia

Ezetimibe co-administered with an HMG-CoA reductase inhibitor (statin) is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia who are not appropriately controlled with a statin alone. Ezetimibe monotherapy is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolaemia in whom a statin is considered inappropriate or is not tolerated.

Prevention of Cardiovascular Events

Ezetimibe is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS) when added to ongoing statin therapy or initiated concomitantly with a statin.

Homozygous Familial Hypercholesterolaemia (HoFH)

Ezetimibe co-administered with a statin, is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g., LDL apheresis).

Homozygous Sitosterolaemia (Phytosterolaemia)

Ezetimibe is indicated as adjunctive therapy to diet for use in patients with homozygous familial sitosterolaemia.

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

Important risks of Ezetimibe, together with measures to minimise such risks are outlined below.

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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 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 Ezetimibe 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 Ezetimibe. 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	• 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 are conditions of the marketing authorisation or specific obligation of Ezetimibe.

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

There are no studies required for Ezetimibe.

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