Summary of the risk management plan for Telmisartan 20 mg & 40 mg & 80 mg tablets

This is a Summary of risk management plan for Zanacodar 20 & 40 & 80 mg Comprimidos, Telmisartan Liconsa 20 & 40 & 80 mg Comprimidos, Mirpresoc 20 & 40 & 80 mg Comprimidos, Meldoc 20 & 40 & 80 mg Comprimidos, Tesgreco 20 & 40 & 80 mg Comprimidos, Terdefel 20 & 40 & 80 mg Comprimidos, Diterpris 20 & 40 & 80 mg Comprimidos[2].

This is a summary of the risk management plan (RMP) for Telmisartan 20 mg & 40 mg & 80 mg tablets [3]. The RMP details important risks of Telmisartan 20 mg & 40 mg & 80 mg tablets, how these risks can be minimised, and how more information will be obtained about Telmisartan 20 mg & 40 mg & 80 mg tablets 's risks and uncertainties (missing information).

Telmisartan 20 mg & 40 mg & 80 mg tablets 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Telmisartan 20 mg & 40 mg & 80 mg tablets should be used.

I. The medicine and what it is used for

This medicine is use in the treatment of essential hypertension in adults and in a prevention of cardiovascular events.

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

Important risks of Telmisartan 20 mg & 40 mg & 80 mg tablets, together with measures to minimise such 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.

[2] Name of the product in the RMS
[3] Please consider name of the product in the RMS (07 products)

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Together, these measures constitute routine risk minimisation measures.

If important information that may affect the safe use of Telmisartan 20 mg & 40 mg & 80 mg tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Telmisartan 20 mg & 40 mg & 80 mg tablets 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 Telmisartan 20 mg & 40 mg & 80 mg tablets. 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	○ Renal dysfunction as a consequence of dual reninangiotensin-aldosterone (RAAS) blockade ○ Sepsis ○ Fetotoxicity ○ Hypoglycaemia (in diabetic patients)
Important potential risks	○ Increase of hepatic - related adverse reactions in the Japanese population ○ Rhabdomyolysis ○ Malignancies
Missing information	○ None

Table 4. List of important risks and missing information

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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of **Telmisartan 20 mg & 40 mg & 80 mg tablets.**