Part VI: Summary of the risk management plan

Active substance (INN or common name):	Articaine / Epinephrine
Name of Marketing Authorisation Holder or Applicant (MAH):	LABORATORIOS NORMON, S.A. LABORATÓRIOS NORMON, S.A.
Product concerned (brand name):	Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable) Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable)

Data lock point for this module	08/03/2022
Version number of RMP when this module was last updated	Not applicable

Summary of risk management plan for

Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG
Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG
Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable)
Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable)
<Articaine / Epinephrine>

This is a summary of the risk management plan (RMP) for Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable). The RMP details important risks of Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable), how these risks can be minimised, and how more information will be obtained about for Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) risks and uncertainties (missing information).

Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) summaries of product characteristics (SmPCs) and its package leaflets give essential information to healthcare professionals and patients on how Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) should be used.

I. The medicine and what it is used for

Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) are authorized for local and loco-regional anaesthesia in dental procedures (see SmPC for the full indication). It contains Articaine / Epinephrine as the active substance and is used as solution for injection.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Measures to minimise risks and the proposed studies for learning more about Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) are outlined below.

Measures to minimize the risks identified for medicinal products, like these ones, 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 patients (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine 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*.

If important information that may affect the safe use of Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable) is not yet available, it is listed under 'missing information'.

II.A List of important risks and missing information

Important risks 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 medicinal products. 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).

Only routine pharmacovigilance and risk minimisation measures are being proposed forArticaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable).

Summary of safety concerns	
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 Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable).

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

There are no studies required for Articaína + Epinefrina Normon 40 mg/ml + 0.005 mg/ml solución inyectable EFG, Articaína + Epinefrina Normon 40 mg/ml + 0.01 mg/ml solución inyectable EFG, Normocain® (40 mg/ml + 0.005 mg/ml solución inyectable), Normocain® (40 mg/ml + 0.01 mg/ml solución inyectable).