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| <b>RISK MANAGEMENT PLAN</b><br>Fenofibrato toLife, Fenofibrato pensa 145 mg comprimidos<br>recubiertos con película EFG, Fenofibrato Pensa | V0.2 | Date: 30 Jan 2025 |
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## **Part VI: Summary of the risk management plan**

## Summary of risk management plan for Fenofibrato toLife, Fenofibrato pensa 145 mg comprimidos recubiertos con película EFG and Fenofibrato Pensa (Fenofibrate)

This is a summary of the risk management plan (RMP) for Fenofibrato toLife, Fenofibrato pensa 145 mg comprimidos recubiertos con película EFG and Fenofibrato Pensa (hereinafter, referred as Fenofibrato pensa / toLife). The RMP details important risks of Fenofibrato pensa / toLife how these risks can be minimised, and how more information will be obtained about Fenofibrato pensa / toLife' risks and uncertainties (missing information).

Fenofibrato pensa / toLife summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how should be used.

Important new concerns or changes to the current one will be included in updates of Fenofibrato pensa / toLife RMP.

### I. The medicine and what it is used for

Fenofibrato pensa / toLife is authorised in adults for:

- Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol.
- Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.
- Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled.

It contains fenofibrate as the active substance and it is given orally.

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

Important risks of, together with measures to minimise such risks and the proposed studies for learning more about Fenofibrato pensa / toLife, 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.

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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 Fenofibrato pensa / toLife are risks that no need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Fenofibrato pensa / toLife. 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).

| <b>Summary of safety concerns</b> |                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Important identified risks        | <ul style="list-style-type: none"> <li>• Cholelithiasis</li> <li>• Pancreatitis</li> <li>• Myopathy/Rhabdomyolysis</li> <li>• Drug-induced hepatitis</li> <li>• Elevations in serum creatinine</li> <li>• Photosensitivity reaction</li> <li>• Venous thromboembolic disease</li> <li>• Interstitial lung disease</li> <li>• Severe cutaneous reactions</li> </ul> |
| Important potential risks         | <ul style="list-style-type: none"> <li>• Increased risk of major adverse cardiac events in women on combined treatment</li> <li>• Increased blood homocysteine levels</li> </ul>                                                                                                                                                                                   |
| Missing information               | <ul style="list-style-type: none"> <li>• Use in the paediatric population</li> <li>• Use during pregnancy and lactation</li> <li>• Use in patients with severe renal impairment</li> <li>• Use in patients with hepatic insufficiency</li> </ul>                                                                                                                   |

## ***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 Fenofibrato pensa / toLife.

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

There are no studies required for Fenofibrato pensa / toLife.