

Summary of risk management plan for Tadalafil Bluefish (tadalafil)

This is a summary of the risk management plan (RMP) for Tadalafil Bluefish. The RMP details important risks of Tadalafil Bluefish, which can be minimised through routine risk minimization measures, and more information will be obtained Tadalafil Bluefish's risks and uncertainties (missing information) through routine pharmacovigilance activities.

Tadalafil Bluefish's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tadalafil Bluefish should be used.

I. The medicine and what it is used for

Tadalafil Bluefish is indicated in adults for the treatment of pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity and in paediatric population for the treatment of paediatric patients aged 2 years and above with pulmonary arterial hypertension (PAH) classified as WHO functional class II and III.

It contains tadalafil as the active substance, and it is given orally as 20 mg film-coated tablets.

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

Important risks of Tadalafil Bluefish, together with measures to minimise such risks and the proposed studies for learning more about Tadalafil Bluefish's 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.

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 Tadalafil Bluefish are risks that 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 Tadalafil Bluefish. Potential risks are concerns for

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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 Adcirca (tadalafil). [MAH: Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ, Utrecht, Netherlands.]

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 Tadalafil Bluefish.

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

There are no studies required for Tadalafil Bluefish.