# Summary Public Assessment Report

# Generics

# Biprenessa 5 mg/5 mg
# Biprenessa 5 mg/10 mg
# Biprenessa 10 mg/5 mg
# Biprenessa 10 mg/10 mg
# film-coated tablets

# bisoprolol fumarate/perindopril arginine

# SK/H/0333/001-004/DC

# Date: November 2025

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bisoprolol fumarate/perindopril arginine, film-coated tablets, 5 mg/5 mg, 5 mg/10 mg, 10 mg/5 mg, 10 mg/10 mg

This is a summary of the public assessment report (PAR) for Bi-Prenessa. It explains how Bi-Prenessa was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Bi-Prenessa.

For practical information about using Bi-Prenessa, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Bi-Prenessa and what is it used for?

Bi-Prenessa is a 'generic medicine'. This means that Bi-Prenessa is similar to a 'reference medicine' already authorised in the European Union (EU) called Bipressil® film-coated tablets (by Les Laboratories Servier).
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Bi-Prenessa 5 mg/ 5 mg and Bi-Prenessa 10 mg/ 5mg are used to treat high blood pressure (hypertension) and/or stable chronic heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs resulting in breathlessness and swelling) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

Bi-Prenessa 5 mg/ 10 mg and Bi-Prenessa 10 mg/ 10 mg are used to treat high blood pressure (hypertension) and/or to reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or an operation to improve the blood supply to the heart by widening the vessels that supply it.

## How does Bi-Prenessa work?

Bi-Prenessa contains two active ingredients, bisoprolol fumarate and perindopril arginine in one tablet:

- Bisoprolol fumarate belongs to a group of medicine called beta-blockers. Beta-blockers slow down the heart rate and make the heart more efficient at pumping blood around the body.
- Perindopril arginine is an angiotensin converting enzyme (ACE) inhibitor. It works by widening the blood vessels, which makes it easier for your heart to pump blood through them.

## How is Bi-Prenessa used?

The pharmaceutical form of Bi-Prenessais film-coated tablet and the route of administration is oral.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The recommended dose is one tablet once daily. Swallow your tablet with a glass of water in the morning before a meal.

In some cases, your doctor may prescribe one half tablet of Bi-Prenessa once daily in the morning before a meal.

The medicine can only be obtained with a prescription.

**What benefits of Bi-Prenessa have been shown in studies?**

Because Bi-Prenessais a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Bipressil® film-coated tablets.
Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

**What are the possible side effects of Bi-Prenessa?**

Because Bi-Prenessa is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

**Why is Bi-Prenessa approved?**

It was concluded that, in accordance with EU requirements, Bi-Prenessa has been shown to have comparable quality and to be bioequivalent to Bipressil® film-coated.
Therefore, the SIDC decided that, as for Bipressil® film-coated tablets (by Les Laboratories Servier)., the benefits are greater than its risk and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Bi-Prenessa?**

A risk management plan has been developed to ensure that Bi-Prenessa is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bi-Prenessa, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Bi-Prenessa**

The marketing authorisation for Bi-Prenessa was granted on 26.06.2025.

The full PAR for Bi-Prenessa can be found on the website. For more information about treatment with Bi-Prenessa, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 11/2025.