Product Information as approved by the CHMP on 15 December 2022, pending endorsement by the European Commission

Annex III

Amendments to the relevant sections of the product information

Note:

This product information is the outcome of the referral procedure to which this Commission decision relates.

The product information may be subsequently updated by the Member State competent authorities, in liaison with the Reference Member State, as appropriate, in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC.

Amendments to the relevant sections of the product information

The valid product information is the final version achieved during the Coordination group procedure with the following amendments (marked as **insertion** or ~~deletion~~ of the text as appropriate) to reflect the agreed wording as provided below:

A. Summary of Product Characteristics

Section 4.1 Therapeutic indications

Strengths: 2,5 mg + 2,5 mg; 5 mg + 2,5 mg; 5 mg + 5 mg; 10 mg + 5 mg; 10 mg + 10 mg

{[Nationally completed name]} is indicated as substitution therapy for treatment of hypertension~~,~~ **and/or** hypertension with coexisting chronic coronary syndrome: ~~(in patients with a history of myocardial infarction and/or revascularisation) and/or chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with ramipril and bisoprolol given concurrently at the same dose level.~~

- in patient with manifest atherothrombotic cardiovascular disease (history of coronary heart disease or stroke, or peripheral vascular disease) or

- diabetes with at least one cardiovascular risk factor, and/or chronic heart failure with reduced systolic left ventricular function (secondary prevention after acute myocardial infarction: reduction of mortality from the acute phase of myocardial infarction in patients with clinical signs of heart failure when started > 48 hours following acute myocardial infarction).

In adult patients adequately controlled with ramipril and bisoprolol given concurrently at the same dose level.

Strength: 2,5 mg + 1,25 mg

{[Nationally completed name]} is indicated as substitution therapy in chronic coronary syndrome (in patients with a history of myocardial infarction and/or revascularisation) and/or chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with ramipril and bisoprolol given concurrently at the same dose level.

B. Package Leaflet

Section 1

{[Nationally completed name]} contains two active ingredients, bisoprolol fumarate and ramipril in one capsule:

- Ramipril 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.
- 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.

{[Nationally completed name]} is used to treat high blood pressure (hypertension) and/or chronic heart failure with left heart chamber dysfunction (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 chronic 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~~.~~**, or diabetes with at least one cardiovascular risk factor.**

Instead of taking bisoprolol fumarate and ramipril as separate capsules, you will take only one capsule of {[Nationally completed name]} which contains both active ingredients in the same strength.