

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Innovace 20 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg of enalapril maleate.

Excipients with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablets

*Product imported from Romania:*

Peach, rounded triangle shaped tablet, one side scored\*, the other side marked MSD 714

\*The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

## 4 CLINICAL PARTICULARS

As per PA23198/005/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/005/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium bicarbonate

Corn starch

Pregelatinised starch Magnesium stearate Lactose monohydrate

Iron oxide yellow (E172)

Iron oxide red (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

### 6.5 Nature and contents of container

Carton with 2 Al/Al blisters of 14 tablets each. 28 tablets per carton.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/208/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 7<sup>th</sup> July 2023

## **10 DATE OF REVISION OF THE TEXT**