Cerba

MEDICAL PRESCRIPTION FORM

CONSULTATION CERTIFICATE / CONSENT TESTING

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CYP2C19 GENOTYPING

IN THE CONTEXT OF TREATMENT WITH MAVACAMTEN

SAMPLING

Sampling date: |_|_|/|_|_|/|_|_|_|_| **Analysis Code: 2C19** **Indication Code: iPG001** **Customer n° :** |_|_|_|_|_| / |_|_|

☐ **EDTA whole blood (5 mL)** *(nature code: SGE)* **OR** ☐ **Buccal cells** *(nature code: CBUC) Please contact us for the collection kit.*

PATIENT

SURNAME ……

FIRST NAME ……

Maiden Name ……

Address ……

City …… Country……

Date of birth: |_|_|/|_|_|/|_|_|_|_|

PRESCRIBER

Stamp Mandatory

Email address: ……

Signature:

Information for the patient

Your doctor has prescribed treatment with Mavacamten (CAMZYOS®)

What is CAMZYOS®?
CAMZYOS® contains the active substance Mavacamten (from the group of cardiac myosin inhibitor) that helps the muscles in your heart to relax, which allows your heart to pump blood more easily throughout your body.

When CAMZYOS® is used?
CAMZYOS® is used to treat obstructive hypertrophic cardiomyopathy (OHCM) in symptomatic adults.

What are the tests needed before treatment?
The rate at which this medicine is metabolized varies between patients, partly due to genetic characteristics. Mavacamten is significantly metabolized, mainly by the cytochrome P450 2C19 enzyme (CYP2C19) (74%). Patients who are poor metabolizers of *CYP2C19* may have increased exposure to Mavacamten (up to 3 times higher rate), which can lead to side effects. For this reason, your doctor has prescribed a *CYP2C19* genetic test to determine your ability to metabolize the therapeutic molecule.

***CYP2C19* Genotyping**
This genetic test should ideally be performed before starting treatment to determine the most appropriate dose. Currently, this test is not reimbursed by Social Security in France

Certificate of Consultation and Information from the Prescribing Physician

I, the undersigned, Dr./Prof. [*First Name, Surname*]……, certify that on this day I have informed the patient :

Mrs./Ms. [*First Name, Surname*]……, Born on [*Date of birth*]……

or his/her parents or legal guardian, about the characteristics of the prescribed genetic test according to the conditions outlined in the French Public Health Code (Articles R1131-4 and 5).

Information and Consent Form for Genetic Testing of an Individual's Characteristics

I, the undersigned, Mr./Ms. [*First Name, Surname*] ……, I hereby confirm that I have received from the physician mentioned above, the information regarding the genetic test proposed to me, to which I consent, and which will be carried out using one or more biological samples taken from me, in order to adapt my therapeutic and medical care.

I have been informed:

- Of all the details stated in the medical consultation certificate.
- Of my right to interrupt this request for examination(s) at any time, to request that the results not be communicated to me, or that any stored samples be destroyed
- That the results are confidential and will be communicated and explained to me during a consultation by the prescribing physician.

I consent to the collection and performance of the examination as part of my medical and therapeutic care

This examination (or these examinations) will be carried out in a medical biology laboratory authorized by the ARS (Agence Régionale de Santé) to perform them. The original of this document will be kept in my medical file. A copy of this document will be given to me as well as to the experts responsible for performing the tests,in the medical biology laboratory under the same conditions as the examination report.
I have had the opportunity to ask all the questions I wished to the physician who prescribed this test, and I have received complete and adequate answers.

Done at ……, On ……

IDENTITY OF THE PATIENT	IDENTITY OF THE LEGAL REPRESENTATIVES ***(Signature)***	PRESCRIBER ***(Signature)***
(Signature) *Surname, Fist Name,*	*Surname, Fist Name, Date of birth:*	*Surname, Fisrt name*
Date of birth:	*Surname, Fist Name, Date of birth:*	
	If the patient is a minor or an adult under guardianship, relationship to the patient:	