ADULT PATIENT INFORMATION SHEET

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Title of the project: Zimino® French Registry
The French registry for the evaluation of Zimino®

Protocol: France-LEVO

N° EUDRACT : 2019-A02903-54

Sponsor: ARCOTHOVA,
SAR Sud – Hôpital Haut-Lévèque
Avenue Magellan 33600 Pessac, France

Information leaflet for Mr or Mrs (First Name – Last Name – Month and Year of Birth):_____

This patient information notice is intended to introduce you to France-Levo, a register set up by the association ARCOTHOVA (Anesthesia-Resuscitation-Heart-Thorax-Vessels) at the request of the High Authority of Health (HAS) to record usage information for all patients treated with levosimendan.

It is important that you read this document which will provide you with the necessary information on the various aspects of this register, which will allow you to decide whether you want your child to participate or not.

You will be provided with a copy of this document.

Madam, Sir,

Orion-Pharma Laboratory holds the market authorization for a drug named ZIMINO® whose active product is levosimendan.

What is levosimendan?

Levosimendan is a drug that acts on the heart and vessels. It is part of inotropic treatments that increase the contraction force of the heart ventricles. In addition, it dilates arterial vessels such as the aorta and peripheral arteries, coronary arteries and pulmonary arteries. Its action consumes very little oxygen and its duration of action, after a continuous injection of 24 hours, is 7 to 9 days, this is what distinguishes it from other inotropic treatments. Your doctor who felt it was necessary to treat you with this medicine suggested that you participate in this registry.

What is France-Levo? What is the purpose of patient monitoring?

France-Levo is a registry, set up in hospitals specialized in cardiovascular surgery, cardiology and intensive care. It aims to record information on “the modalities of use of ZIMINO in real life” in order to carry out “a representative study of the practices of use of ZIMINO in France”.

Who can be registered in France-Levo?

The HAS requested that all patients treated with levosimendan (ZIMINO) be registered in the France-Levo registry.

How long will the study take?

You will be assessed during the reference hospitalization and at J30 (±15) and J90 (±15) after you leave the hospital. Follow-up can be a phone call or a hospital visit depending on your doctor's practice.

Quelles données seront enregistrées dans France-Levo ?

If you receive treatment with ZIMINO, your doctor will collect in the electronic register France-Levo data on your medical history, the results of your clinical examination, the treatment you received, its tolerance and other important information related to your medical-surgical management. These data are usually found in patients' medical records.

You may refuse to allow certain medical information about you to be collected in this registry without any impact on your medical management. However, even if you refuse, the following data will be recorded in order to meet the requirements of completeness of the register requested by the HAS: hospital centre, year of birth, sex, date of hospitalization and types of procedures performed.

Participating in France-Levo will have no impact on the treatment and general medical surveillance of your heart disease. No additional tests (in addition to those prescribed by standard treatment) will be required. France-Levo is simply a centralized record of information required by the health authorities that your doctor would have recorded in your medical record anyway.

How many patients will be registered in France-Levo?

Depending on the number of prescriptions and epidemiological data, it is estimated that 600 patients will be included in the registry over a period of one year.

Where will the France-Levo register information be stored?

The information about you will be stored online and stored in a secure database in France until the end of the search. This database will then be archived for a period of time in accordance with the regulations and not exceeding 15 years.

On the subject of confidentiality

The data collected in this study will be processed electronically for the purposes of extraction, validation, statistical analysis, and editing of the results in accordance with the objective set out below on behalf of ARCOTHOVA. They will be treated confidentially, in coded form and without mention of his first and last name. The resulting computer file was submitted to the National Commission for Informatics and Freedoms (CNIL).

In accordance with the French law "Informatique et Libertés" n°78-17 of 6 January 1978 as amended and with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation or GDPR), you have a right of access, rectification,

erasure or portability of its data or you may object to the processing of its data by the Promoter or request a limitation thereof. You also have the right to define the fate of personal data in the event of disappearance.

You can exercise this right of access to all of its medical data under the provisions of article L.1111-7 of the Public Health Code: either by contacting the study doctor, either through a doctor of your choice (your doctor may be the intermediary between you and the study doctor) or by contacting " ARCOTHOVA, secretariat SAR Sud, CMC Magellan, Hôpital Haut-Lévèque – Avenue de Magellan – 33604 PESSAC Cedex, France".

The results of this register can be transmitted in the form of study reports to the HAS and the ORION-PHARMA laboratory which distributes ZIMINO. These reports will contain only information grouped in the form of statistical results (numbers, percentages, etc.), the information transmitted in this way will not contain information that will allow us to find our identity. The data contained in his medical file will be treated in strict confidentiality.

The study is in accordance with the MR004 reference methodology and does not require the opinion of the Expert Committee for Research, Studies and Evaluations in the field of Health (CEREES) or specific authorization of the CNIL. Studies conforming to MR004 are not to be submitted to a Committee for the Protection of Persons (CPP).

In accordance with French law, the documents of this study were registered on the National Register of Studies under Reference Methodology of the National Institute of Health Data (INDS) before its implementation (registration of 14/01/2020 under MR 0222140120).

What is your contact?

If you have any questions or would like more information on the France-Levo registry, you are invited to contact the study doctor who prescribed ZIMINO to your child.

Specificities for Minor and Major Protected Patients:

Although ZIMINO's marketing authorization is reserved for adults. Children are also covered by this register.

If the patient is a protected adult or a person is unable to express his or her consent, this briefing note will be presented either to the legal official or to a family member respectively. The purpose of this information note is to inform the patient about the Registry and his or her rights to the collection and processing of his or her health data. ZIMINO may be administered to the patient in an emergency situation, but in this case the legal representative of the protected adult or the conscious patient may object to the collection of his health data, and request a posteriori rectification or deletion of its data.

Thank you for taking the time to read the information on the France-Levo register. Do not hesitate to ask the study doctor any questions that come to mind about this registry, and he will answer them before, during and after his hospitalization.

The Scientific Committee of the study and the representatives of ARCOTHOVA

Name of "study physician":_____

Doctor's Phone Number and Service Phone Number (in case of physician unavailability):_____

I, the undersigned Doctor (first and last name)_____ confirms (check the boxes below):

Presenting the France-Levo registry to my patient.

- That the patient had the opportunity to ask questions about the registry and I answered all of his questions to the best of my ability.
- That the patient has given his consent to participate in the registry.
- A copy of the briefing note was provided to the patient.

Signature and stamp of the "study physician" confirming patient participation agreement

as of : ____/ ____/ 20____

Signature and stamp: