



designed by **BIOCORP**
LABORATOIRES
for **Théa**

PRIVACY POLICY

CONNECTDROP® application

— English —

Firmware version 2.0.0 and later



Under your participation in the GRANITE study, some of your personal data will be collected via the CONNECTDROP® mobile application.

For full information on all the data collected for this study, please refer to the document you received from your healthcare professional.

The processing of your personal data is carried out under the responsibility of Laboratoires Théa (hereafter referred to as “Théa”), in its capacity as study sponsor. Théa agrees to ensure the confidentiality and security of your personal data and to comply with the applicable regulations, namely:

- the French Data Protection Act N° 7817 of 6th January 1978.
- EU Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data, and on the free movement of such data, of 27th April 2016, referred to as the “**RGPD**”.

All data concerning your participation in this study will be kept strictly confidential and, to the extent permitted by applicable laws and/or regulations, will not be disclosed.

• **WHAT CONSTITUTES PERSONAL DATA?**

Personal data is any information relating yourself that can be used to identify or re-identify you, directly or indirectly. This may be your name, your age, your health data or an ID number.

Under this study, we process data relating to your health and your use of the CONNECTDROP® mobile application. This Privacy Policy describes the conditions under which your personal data will be collected and utilised when you use the CONNECTDROP® mobile application.

• **WHY DO WE COLLECT YOUR PERSONAL DATA AND WHAT IS THE LEGAL BASIS FOR THIS PROCESSING?**

The processing of your personal data is a necessary part of study execution and meets the legitimate aims pursued by Théa (Article 6.1.f) of the General Data Protection Regulation), namely, to assess the observance of your treatment via the CONNECTDROP® mobile application.

This processing is permitted as it is necessary for scientific research purposes (Article 9.2.j) of the General Data Protection Regulation).

• **WHAT HAPPENS IF YOU REFUSE TO SUPPLY YOUR PERSONAL DATA?**

Given that the collection of your personal data is necessary to study execution, if you do not wish to share your personal data we will not be able to include you in said study.

• **WHICH DATA WILL BE COLLECTED ABOUT YOU?**

The following data concerning you will be collected during your utilisation of the CONNECTDROP® mobile application:

Data collected and transmitted by the device to the CONNECTDROP® mobile application:

- Date and time of instilling the drops
- Bottle position
- Device serial number

The information that you entered in the CONNECTDROP® mobile application:

- Surname, first name and date of birth
- Email address
- Telephone number (2-factor authentication)

- Treatment name
- Your consent to the General Terms & Conditions of Use
- Date the bottle was opened

Usage data collected by the application:

- Date and time of pairing the application with the device
- Date and time of the application's connection to the device
- Date and time that the application recovers the data on each instillation recorded by the device
- Date and time of accessing the details in each tile (number of instillations, time interval, bottle position)
- Date and time of accessing bottle management data
- Date and time of editing the report
- Date and time of viewing "Tuto" videos
- Date and time of accessing the user guide
- Date and time of the notification "Bravo! You are taking your treatment correctly"
- Date and time of the notification "no data recorded in the last 3 days"

• HOW LONG ARE YOUR PERSONAL DATA KEPT?

Your personal data collected via the CONNECTDROP® mobile application will be stored in a certified Health Data Hosting Provider backup space for twelve (12) months following signature of the final Study report].

Throughout the study, the sponsor or its authorised subcontractors will retrieve the data and store it in their information system for a period of two years after final publication of study findings or, if these are not published, until the date of signature of the final study report. They will then be archived in a paper or electronic format for a maximum period of twenty years.

• WHO HAS ACCESS TO YOUR PERSONAL DATA?

When collecting your personal data, your doctor will link a code number with your identity (surname, first name). Only your doctor and a list of authorised persons will have access to the document that links your identity to the code number you have been assigned. This document will be kept in a safe place to ensure that you can be identified and contacted in an emergency. Therefore, only a limited number of people have access to your directly identifiable data. All other persons only have access to your indirect identification data (code number).

Laboratoires Théa agree to comply with current regulations governing the protection of personal data collected during their studies and also agree to ensure that your personal data, whether directly or indirectly identifiable, is only accessible to certain authorised individuals, including the following:

• WHO HAS ACCESS TO YOUR DIRECTLY IDENTIFIABLE PERSONAL DATA?

- Your doctor and the healthcare professionals participating in the study who have access to your medical file, as well as the personnel acting under their responsibility or authority;
- The persons responsible for quality control who check the authenticity and consistency of the study data under strict conditions of security and confidentiality, with restricted access limited to the time necessary to complete their mission;
- Laboratoires Théa's designated Data Protection Officer should you contact them (see below for the details on how to contact the Data Protection Officer);
- National or international competent authorities and/or ethics committees who are responsible for ensuring that the study is conducted in accordance with applicable laws and regulations;
- Under strict conditions, certain Laboratoires Théa subcontractors missioned, where necessary, to reimburse your expenses and/or pay your indemnities, to follow you up under the study (e.g.: sending of SMS to complete a questionnaire) or to make home deliveries and pick-ups concerning the products, equipment and samples necessary for study execution. These subcontractors cannot access your personal health data.

• WHO HAS ACCESS TO YOUR INDIRECTLY IDENTIFIABLE PERSONAL DATA?

- Laboratoires Théa, as the study sponsor, together with any persons acting in Laboratoires Théa's name under strict conditions of security and confidentiality with restricted access;
- The study's lead scientist;
- The professionals involved in the study;
- The staff at companies belonging to Group Théa whose participation is necessary to process the data under the study;
- Persons tasked with collecting, performing quality controls, processing and analysing the data;
- Persons responsible for regulatory affairs and for registering the study with the competent authorities;
- National or international competent authorities and/or ethics committees who are responsible for ensuring that the study is conducted in accordance with applicable laws and regulations;
- Authorised personnel acting under the responsibility of the insurance agency guaranteeing the sponsor's civil liability, in application in particular of Article L. 1121-10 of the CSP (Public Health code);
- Laboratoires Théa authorised subcontractors, under strict conditions of security and confidentiality, as well as their hosting providers, to ensure the storage, archiving and security of your personal data, in accordance with the obligations regarding the confidentiality, security and survivability of such data.

• YOUR RIGHTS OVER YOUR PERSONAL DATA

You have several rights regarding the processing of your personal data. These rights include the following:

Access: you have the right to request access to your personal data. However, this access right may be limited during the course of the study.

Correction: you have the right to request the correction of incomplete or inaccurate personal data that we hold about you.

Deletion: in certain circumstances, you have the right to ask us to delete or erase your personal data. There are, however, exceptions where we may refuse a request for deletion, such as where said personal data is necessary regarding compliance with French law or if it is relevant to claims.

Restriction: you have the right to ask us to suspend the processing of certain personal data about you, in particular if you wish us to establish their accuracy.

Objection: you have the right to challenge the fact that we process personal data on the grounds of legitimate interest (or the interest of third parties). However, we may be authorised to continue to process your personal data on the basis of our compelling legitimate interests or where it is justified by legal claims.

Use of your personal data after your death: you have the right to determine how your personal data will be used after your death.

You also have the right to file a complaint with a personal data protection supervisory authority; in France, the Commission Nationale de l'Informatique et des Libertés (CNIL).

• HOW CAN YOU EXERCISE YOUR RIGHTS?

If you have any queries concerning the processing of your personal data or if you wish to exercise any of the rights mentioned above, please contact **your doctor or the healthcare professional** participating in the study, who will then get in touch with Laboratoires Théa.

Please note also that Laboratoires Théa has appointed a Data Protection Officer (DPO), whose details are as follows: dpo@theapharma.com or Laboratoires Théa, DPO, Service Juridique, 12 rue Louis Blériot, Z.I. du Brézet, 63100 Clermont-Ferrand, France.