

PRIVACY POLICY

OT4B SAS
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The following policy applies to the processing of personal data ('personal data' or 'data') carried out by OT4B in the course of its activities.

This privacy policy may be adapted in accordance with the legislative and regulatory context and the recommendations issued by the Commission Nationale de l'Informatique et des Libertés (CNIL), the French data protection regulator.

1. LEGAL FRAMEWORK

The processing of personal data within the European Union is governed by the 'General Data Protection Regulation' (GDPR) of 27 April 2016 ([Regulation \(EU\) 2016/679](#)) and in France by [Law No 78-17 of 6 January 1978 on data processing, files and freedoms \(as amended\)](#).

2. PROCESSING OF PERSONAL DATA BY OT4B

What are personal data?

Personal data means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified directly (e.g. surname/first name) or indirectly (e.g. telephone number, IP address or voice recording/image). The potential to identify a natural person may result from one item of data or a combination of several items of data.

Data collection and use by OT4B

OT4B ensures that the principle of data minimisation is applied by collecting and processing only data that are adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (management of staff, management of contacts and contracts with its partners including healthcare personnel, fulfilment of pharmacovigilance obligations, monitoring of patients receiving specific treatments (see below), management of optional cookies used on the site <https://www.ot4b.com>, etc.).

You can contact us for further details about the various data processing operations carried out by OT4B and, in accordance with CNIL Decision No 2022-106 of 22 September 2022, you can consult in the Annex the information notice providing details of the data processing carried out in relation to the compassionate use program conducted in France with Oxytocin 44.44 IU/mL nasal spray solution.

Basis and objectives of processing

OT4B ensures that its processing of personal data is lawful and that each processing operation is supported by a relevant legal basis:

- the data subject has given consent to the processing of his/her personal data for one or more specific purposes;

- processing is necessary for the performance of a contract to which the data subject is party or for the performance of pre-contractual measures at the data subject's request;
- processing is necessary for compliance with a legal obligation to which the controller is subject;
- processing is necessary in order to protect the vital interests of the data subject or of another natural person;
- processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
- or processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party.

OT4B keeps personal data for no longer than is necessary for the purposes for which those data are processed.

Data recipients

In most cases, OT4B will not transfer data outside the European Union. Any transfers that might be necessary will comply with the requirements of the GDPR.

OT4B may be required to communicate certain data to service providers and/or subcontractors, after ensuring that sufficient guarantees are provided regarding compliance with regulations on the protection of personal data processed on behalf of OT4B.

OT4B may also need to communicate data to legal or administrative authorities, in accordance with the applicable legal requirements.

Rights of data subjects

The individuals whose data are processed have the following rights in relation to the data, depending on the circumstances and the applicable legislation:

Right of access: the right to obtain access to information processed by OT4B.

Right to rectification: the right to request rectification of your information if it is inaccurate or incomplete.

Right of withdrawal: the right to request the erasure or deletion of your information if there are no compelling reasons for OT4B to continue using it.

Right to restriction of processing: the right to 'block' or prevent further use of your information in certain circumstances.

Right to data portability: in certain circumstances, the right to obtain and use your data in a structured, commonly used and machine-readable format.

Right to object: in certain circumstances, the right to object to certain types of processing.

Please note: these rights may be restricted based on requirements linked to the purpose for which the data are processed and the basis on which they are processed.

To exercise your rights or ask any questions, please contact OT4B in writing at the above address or by e-mail at **dataprivacy@ot4b.com**. Please give precise details about the data concerned and the reasons for your request.

In accordance with Article 15(3) of the GDPR and where a request is manifestly excessive OT4B may:

- charge a reasonable fee taking into account the administrative costs of providing the information or communication or taking the action requested, or*
- refuse to act on the request.*

Updating the personal data protection policy

This policy might need to be updated. For this reason, OT4B encourages you to regularly check its website www.ot4b.com.

[Annex: Information notice providing details of the data processing carried out in relation to the compassionate use program conducted in France with Oxytocin 44.44 IU/mL nasal spray solution.](#)

Information notice intended for patients' legal representatives on processing of patients' personal data

A medicinal product dispensed under a compassionate access authorisation has been prescribed. This involves processing personal data on patients' health. These personal data comprise information about the patient, their health and lifestyle.

This document tells you about the personal data collected and how they are processed, i.e. what they will be used for. The data controller is OT4B as holder of the compassionate access authorisation.

What are these data used for?

To be able to obtain a compassionate access authorisation, a medicinal product must fulfil several criteria, particularly that of presenting more benefits than risks and that the patient needs treatment quickly without being able to wait for a Marketing Authorisation. The personal data collected (see detail below) will make it possible to continually assess if these criteria are still fulfilled.

Which law covers the data processing?

This data processing is based on a legal duty imposed on the company, the data controller (Article 6.1.c of the [GDPR](#)) as set out in Articles [L. 5121-12 et sequor of the French Public Health Code](#) relating to the compassionate access framework for medicinal products.

Collection of health data is justified by public interest in the field of healthcare (Article 9.2.i) of the GDPR).

What data are collected?

The doctor and pharmacist who have issued the medicinal product will be required to collect the following personal data whenever necessary to forward to OT4B (and its potential subcontractors (contract research organisation)):

- identification: number, the first three letters of the last name and first two letters of the first name, sex, weight, height, age, full date of birth details (in a paediatric context);
- information about the state of health: in particular, the history of the disease, personal or family history, other diseases or treatments;
- information about the conditions for use of the medicinal product, including in particular: the identity of healthcare professional involved (prescribing doctors and dispensing pharmacists, etc.), other treatments, information about procedures for prescribing and using the medicinal product;
- pseudonymised radiology examinations including an identification number;

- efficacy of the medicinal product;
- nature and frequency of adverse reactions of the medicinal product (these are the unexpected and unpleasant consequences of the treatment: pain, nausea, diarrhoea, etc.);
- reasons for potential discontinuation of treatment.

For some treatments, data may be collected from the patient's immediate family (partner, forebears and descendants, etc.), for example the efficacy and tolerance of the treatment or the carer's quality of life.

You may also be invited to complete questionnaires yourself about your quality of life.

Who receives the data?

The confidential information will be sent to authorised staff of OT4B and its potential subcontractors (contract research organisation) in pseudonymised form. **The patient will only be identified by the first three letters of their last name and the first two letters of their first name, and their age.**

This information will be processed only for the purposes described above. A report of this information, called a progress update report, and a summary of this report are sent by OT4B and to the French national agency for the safety of medicines and health products (ANSM) as well as to the designated Regional Pharmacovigilance Centre, in order to monitor the compassionate access on a national level.

These reports may also be sent to other Health Agencies (particularly those of the USA (Food and Drug Administration) and Europe (European Medicines Agency) as part of the assessment of the medicinal product).

The summaries of these reports may also be sent to the doctors who prescribed the medicinal product, the pharmacists who dispensed it and to anti-poison centres.

This progress update report and the summary report will contain no information making it possible to identify the patient.

A central reading report for each swallowing radiology carried out will be sent, pseudonymised, to the prescribing centre.

Transfer outside the European Union

The data may be transferred to organisations located outside the European Union when such transfer is strictly necessary for data processing.

To this end, OT4B implements the necessary guarantees to protect personal data protection rights, irrespective of the country where the personal data are transferred.

In particular, the following guarantees will have been implemented by OT4B: if data need to be transferred to a country outside the European Union, a contract following the standard contractual clauses drawn up by the European Commission will be signed between OT4B and the company(-ies) receiving the transferred personal data.

You have the right to ask OT4B for a copy of these guarantees.

How long are the data retained?

The personal data are retained for a period of 2 years for active use. The data will then be archived for 15 years. At the end of these time periods, the data will be deleted or anonymised.

Will the data be published?

The competent health authorities publish, on their website, a summary of the progress update report of information collected to assess the medicinal product.

Summaries of the results may also be published in scientific journals.

None of these published documents will allow the patient to be identified.

Can or could the personal data be reused?

- 1) The personal data collected (including swallowing radioscopy examinations) as part of the compassionate access authorisation (in pseudonymised form) may be shared with the Prader-Willi Syndrome reference centre (Toulouse University Hospital), which controls a clinical database on Prader-Willi Syndrome. Thanks to the quantity of data it holds, this database is improving knowledge of this rare disease. The data entered in this database are processed under the sole responsibility of the Prader-Willi Syndrome reference centre. In advance of forwarding any data, OT4B has agreed a protocol with Toulouse University Hospital, under the terms of which Toulouse University Hospital undertakes to provide an adequate level of protection for the data sent.

You can refuse to allow reuse of data at any time, by contacting OT4B (e-mail: dataprivacy@ot4b.com), who will be responsible for alerting the person in charge of personal data at Toulouse University Hospital;

Whatever your decision, it will not interfere with administration of the medicinal product under compassionate access.

- 2) Your personal data may also be used subsequently for research, a study or assessment in the healthcare field. This research will be done under conditions authorised by the General Data Protection Regulation (GDPR) and French law of 6 January 1978, as amended, known as the *loi informatique et liberté* (data processing and freedoms law), and after completing the necessary formalities with the CNIL (French Data Protection Agency). In this context, the data may be used in association with other information about you. This means that your personal data collected under compassionate access may be combined with data from the French national health data system (SNDS), which combines several health databases (such as Medical Insurance and hospital data).

At any time, you can refuse to allow reuse of data for research purposes by contacting OT4B (e-mail: dataprivacy@ot4b.com).

Whatever your decision, it will not interfere with administration of the medicinal product under compassionate access.

- 3) Information about a new research study based on the data will be available on the Health Data Hub website, which publishes a summary of the research protocol for all projects submitted to it: <https://www.health-data-hub.fr/projets>.

What possible rights and recourse do you have?

The doctor who prescribed the medicinal product under compassionate access (or the doctor who dispensed the medicinal product) is the primary contact person to exercise rights over personal data.

You can ask to:

- view personal data;
- modify it;
- restrict the processing of certain data.

Nonetheless, if you accept treatment with a medicinal product dispensed under a compassionate access authorisation, you cannot oppose the personal data listed above being sent or request its deletion. The right of deletion and the right to portability also do not apply to this processing.

You can also contact the person responsible for processing personal data at OT4B at the following address dataprivacy@ot4b.com to exercise these rights, which entails sending the patient's identity to OT4B.

You can also complain to the French Data Protection Agency (CNIL), in particular via its website www.cnil.fr.