**CIDOFOVIR EXPOSURE STUDY**

**Patient Information Sheet**

**and**

**Informed Consent Form**

**Study Title**

Cidofovir Exposure Study

**Sponsors**

Tillomed Laboratories Limited

Tillomed Pharma GmbH

Laboratorios Tillomed Spain SLU

**Prescriber’s Name:**

**Prescriber’s Contact Number:**

**PATIENT INFORMATION SHEET**

In this document, the following terminology is used*:*

“**Cidofovir**” means Tillomed’s Cidofovir 75 mg/ml concentrate for solution for intravenous infusion

“**Data Controller**” means the Sponsors, represented by Tillomed Laboratories Limited (the Lead Data Controller), which is authorised to administer the Study on behalf of all the Sponsors.

“**EMA**” means the European Medicines Agency.

“**GDPR**” means the General Data Protection Regulation.

“**Guardian**” means the person who is legally responsible for the Patient, where the Patient is under 18 or lacks legal capacity to consent to participation in the Study.

“**Informed Consent Form**” means the form of the same name attached to this Patient Information Sheet.

“**Lead Data Controller**” means Tillomed Laboratories Limited.

“**Notice of Withdrawal”** means the form of the same name attached to this Patient Information Sheet.

“**Patient**” means the person prescribed Cidofovir and taking part in the Study.

**“Prescriber**” means the doctor or pharmacist who is treating You.

“**Registry**” means the Cidofovir Exposure Registry which is a database for collecting and storing patients’ medical and other information in connection with treatment using Cidofovir for use in medical research.

“**Secondary Party**” means any party with which Patients’ baseline and follow up data is shared, for example the Lead Data Controller’s pharmacovigilance service provider, a statistician who will analyse the data in the Registry to identify any trends, the EMA and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance and other researchers

“**Sponsors**” means Tillomed Laboratories Limited, Tillomed Pharma GmbH and Laboratorios Tillomed Spain SLU which are jointly conducting and funding the Study on the direction of the EMA.

“**Study**” means a non-interventional study to monitor what type of patients are treated with Cidofovir, what it is used for, and to compare patterns and rates of adverse reactions between patients who are prescribed it for its “on label” (licensed) use and those who are prescribed it to treat an “off label” (unlicensed) symptom. The Study is being undertaken in the United Kingdom, Germany, Belgium and Spain.

“**Unique Study Reference Number**” means a unique number assigned to each Patient for the purposes of the Study only.

“**You**” means the Patient.

**Voluntary nature of the Study and right of withdrawal**

You, and your Guardian (if applicable), should be given enough time to read and understand the information in this document and to ask your Prescriber to explain anything You do not understand. You may also wish to discuss it with your family before consenting to take part.

Your participation in the Study is entirely voluntary.

If You choose not to participate, your medical care and your relationship with your Prescriber will not be affected. Your Prescriber will still take care of You.

If You choose to participate, You (or your Guardian, if applicable) must consent to the use of your information as described in this Patient Information Sheet by signing the Informed Consent Form at the back of the document. If You (or your Guardian) do not sign them, You will not be able to participate.

**You (or your Guardian, if applicable) may withdraw consent at any time during the course of the Study, without having to provide any explanation, by completing a Notice of Withdrawal and sending it to your Prescriber, or otherwise notifying your Prescriber.** Your Prescriber’s contact details are on page 7 of this document**.** (See “What will happen to your information if You withdraw from the Study?”)

If You have any questions after reading this document, please contact the Prescriber before signing the Patient Information Sheet and Informed Consent Form.

**What is the Cidofovir Exposure Study?**

Cidofovir was first approved for use in Europe more than ten years ago and is currently licensed for the treatment of a condition called cytomegalovirus (CMV) retinitis (a disease of the eye), occurring in Human Immunodeficiency Virus (HIV) infected patients.

The EMA requires additional monitoring of Cidofovir through an exposure registry study in the United Kingdom, Germany, Belgium and Spain. The objectives of the Study are to:

* monitor what type of patients are treated with Cidofovir
* monitor what Cidofovir is used for, and
* compare patterns and rates of adverse reactions between Patients who are prescribed Cidofovir for its “on label” (licensed) use and those who are prescribed it to treat an “off label” (unlicensed) symptom.

Medical and other information about Patients exposed to Cidofovir will be stored in the Registry to understand which conditions Cidofovir is used to treat and its side effects.

The information will be gathered during the course your Cidofovir treatment. You will not be charged for participating in the Study.

**What makes You eligible to participate in the Study?**

You can participate in the Study if You:

* are prescribed Cidofovir; and
* have signed the Patient Information Sheet and Informed Consent Form (or it is signed by your Guardian on your behalf).

**How many subjects will be involved in the Study?**

The Study will be conducted in four countries, namely United Kingdom, Germany, Belgium and Spain. Many patients in those countries are prescribed Cidofovir but not all of them will be given the opportunity to participate, and, of those given the opportunity to participate some will choose not to join the Study.

**Study duration**

Your participation in the Study will be as long as You are treated with Cidofovir (see “Voluntary nature of the Study and right of withdrawal”) or until the Study is terminated (see **“**Termination of Study**”)**.

**What information will be collected about You?**

If You consent to take part in the Study, your Prescriber will record some information about You as follows:

* Month and year of birth
* Gender
* Medical history
* Your treatment details (e.g. the medical condition for which You are prescribed Cidofovir, how much Cidofovir You take, how it is administered)
* Results of your laboratory tests (blood and urine)
* Details of other medication, whether given to You along with Cidofovir treatment or for another condition

This is your “baseline data”.

Further data will be collected whenever You attend the hospital again for reasons connected with your treatment with Cidofovir.

Your “follow-up data” will include:

* Your treatment details (e.g. the medical condition for which You are prescribed Cidofovir how much Cidofovir You take, how it is administered)
* Results of your laboratory tests (blood and urine);
* Details of other medication, whether given to You along with Cidofovir treatment or for another condition;
* Details of any adverse reaction You suffer
* The outcome of the treatment.

This is your “follow up data”.

**What will happen to the information You provide and how will your privacy be protected?**

Before You agree to participate in the Study, it is important that You understand what will be done with the information You provide and how your privacy will be protected.

Your Prescriber will be allotted a Unique Study Reference Number for You which will enable him/her to upload your signed Patient Information Sheet and Informed Consent Form and enter your baseline and follow up data in the Registry via a secure web based portal.

Your Patient Information Sheet and Informed Consent Form and (where applicable) your Notice of Withdrawal will be accessible by only your Prescriber, the Lead Data Controller and its drug safety monitoring consultant who is embedded in the Lead Data Controller’s Study team.

Subject to the next paragraph, no Secondary Party with which your baseline and follow up data is shared will be able to identify You because You will be referred to only by your Unique Study Reference Number.

If:

* You suffer an adverse reaction that must be reported to the EMA AND You give your consent to your Prescriber releasing your name and contact details to the Lead Sponsor’s pharmacovigilance provider (PV provider) (see below); or
* the Lead Data Controller’s IT support provider needs to correct a technical issue with the Registry

your identity will be known to the PV provider and may be seen by the IT support provider.

If You suffer an adverse reaction, ordinarily it will not be necessary to identify You in the information provided to the Lead Sponsor’s pharmacovigilance provider (PV provider) which collates the report required to be made by law[[1]](#footnote-1) to the EMA. However, in the unlikely event your Prescriber believes it is necessary for the PV provider to contact you directly, your Prescriber will first obtain your explicit consent to releasing your identity and contact details to the PV provider. In any event, your identity will not be revealed in the report sent to the EMA.

Your baseline and follow up data will be used to meet the Study objectives (see “What is the Cidofovir Exposure Study?”).

If data from the Registry, is published in scientific journals or presented at scientific meetings, You will not be identifiable.

Unless You withdraw from the Study (see “What will happen to your information if You withdraw from the Study”), Your Patient Information Sheet and Informed Consent Form, baseline and follow up data will be kept for the lifetime of the marketing authorization (licence) for Cidofovir plus a further 10 years. This is because the Sponsors have a legal obligation to retain it for this long[[2]](#footnote-2).

Your Patient Information Sheet and Informed Consent Form and Notice of Withdrawal will be retained by your Prescriber in accordance with his/her hospital’s policies.

**What will happen to your information if You withdraw from the Study?**

You are entitled to withdraw your consent to participating in the Study (see “Voluntary nature of the Study and right of withdrawal”).

If You (or your Guardian acting on your behalf) withdraw consent, your baseline and follow up data will be deleted from the Registry.

If You have suffered an adverse reaction and consented to your Prescriber releasing your name and contact details to the Lead Data Controller’s pharmacovigilance provider (PV provider), the PV provider will delete those details so that the remaining information it holds about your adverse reaction is anonymised.

The Lead Data Controller has a legitimate interest in retaining copies of your signed Patient Information Sheet and Informed Consent Form and your Notice of Withdrawal for its records. They will be retained for the lifetime of the marketing authorization (licence) for Cidofovir plus a further 10 years. Your Prescriber will also keep copies of these documents.

**What are your rights in relation to the privacy of your information?**

You have a number of rights under the GDPR. You can:

* Access and obtain a copy of your information
* Require the Lead Data Controller to change incorrect or incomplete information
* Require the Lead Data Controller to delete or stop processing your information

If You would like to exercise any of these rights, please contact the Lead Data Controller by emailing [companysecretary@tillomed.co.uk](mailto:companysecretary@tillomed.co.uk).

You can also withdraw your consent to processing of your baseline data and follow-up data, You can do this by contacting the Lead Data Controller as above, by completing the Notice of Withdrawal and sending it to your Prescriber or by telling your Prescriber to inform the Lead Data Controller. If You do this, You will not be able to continue to participate in the Study.

If You believe the Lead Data Controller has not complied with your GDPR rights, You can complain to the Information Commissioner.

**Will You be updated about any new findings related to the Study?**

If any new information comes to light during the Study that may affect your decision to continue participating, or may raise some concern, You or your Guardian will be informed about the new finding(s) by your Prescriber.

**Anticipated benefit**

Participation in the Study is not likely to benefit You personally, medically or financially. However, your participation may help the Sponsors, the EMA and researchers gain information about the condition for which You are being treated. This may improve treatment of the condition from which You suffer.

**Risks of participating**

There is minimal risk in taking part in the Study. You can withdraw from the Study at any time (see “Voluntary nature of the Study and right of withdrawal”).

**Participation of minors and adults unable to consent**

You may consent to participate in the Study if You are 18 years of age or over, understand the Patient Information Sheet and Informed Consent Form and sign them.

If You are younger than 18 (a “minor”) or otherwise have a Guardian to represent You, your Guardian may consent to your participation. If they are prepared to give consent, they must sign the form on your behalf.

If you are the Guardian of a Patient, you will need to explain the nature of the Study to them and sign the Patient Information Sheet and Informed Consent Form on their behalf.

If You are a minor for whom a Guardian consents to participation in the Study and You celebrate your 18th birthday while participating in the Study, You must sign a Patient Information Sheet and Informed Consent Form to continue taking part.

**Termination of Study**

You may be taken off the Study without your consent (or that of your Guardian, if applicable) if your Prescriber thinks that further participation may be unsuitable for You.

In addition, the Sponsors or the EMA may terminate the Study for any of the following reasons:

* Inability to recruit enough Patients to the Study
* Failure of the Lead Data Controller to adhere to the instructions laid down in the Study protocol
* Poor quality of data obtained during the Study;
* Administrative decision.

**Who do I contact with questions?**

If You or your Guardian have any questions about the Study or your participation in the Study, please contact your Prescriber.

To inquire about your data protection rights as a participant in the Study, please contact the Lead Data Controller.

|  |  |
| --- | --- |
| **Prescriber** | Name: |
| Address: |
| Phone: |
| Email: |
| Fax: |
| **Lead Data Controller** | Tillomed Laboratories Limited |
| 220 Butterfield  Great Marlings  Luton  LU2 8DL |
| Phone: 01480 402400 |
| Email: companysecretary@tillomed.co.uk |

**Informed Consent Form**

**Study Title:** Cidofovir Exposure Study (“**Study**”)

|  |  |  |
| --- | --- | --- |
|  |  | Please check  the box |
| 1 | I confirm that I have read the Patient Information Sheet for the Study and  have had the opportunity to ask questions and clarify anything I do not understand. |  |
| 2 | I understand that my participation in the Study is voluntary and that I am free to  withdraw at any time, without giving any reason, and that my medical care  and relationship with my Prescriber will not be affected. |  |
| 3 | I consent to the transfer of my personal data to the Lead Sponsor by my Prescriber. |  |
| 4 | I consent to the use and disclosure of baseline data and follow-up data about me as  set out in the Patient Information Sheet for the Study |  |
| 5 | I agree to take part in the Study. |  |

I have read the above and confirm it is presented in a language that I understand well. I understand that I will be given a signed copy of the Patient Information Sheet and this Informed Consent Form.

**Name of Patient**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |

**Name of Guardian, if applicable**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |

**Signature of the Patient/Guardian**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Notice of Withdrawal**

**Name of Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I wish to withdraw from the Study and withdraw my consent to the processing of my personal data.

I understand that:

* no further information about me will uploaded to the Cidofovir Exposure Registry;
* my baseline data and follow up data will be deleted in accordance with the section in the Patient Information Sheet entitled “What will happen to your information if You withdraw from the Study?”;
* my signed Patient Information Sheet and Informed Consent Form, together with my Notice of Withdrawal will be retained in the Registry in accordance with the section in the Patient Information Sheet entitled “What will happen to your information if You withdraw from the Study?”
* if I have suffered an adverse reaction and I have consented to the provision of my name and contact details to the Lead Data Controller’s pharmacovigilance provider (PV provider), the PV provider will delete those details so that the remaining information it holds about me is anonymised.

**Name of Patient**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |

**Name of Guardian, if applicable**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |

**Signature of the Patient/Guardian**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**For Prescriber’s use** **(to be completed prior to uploading to Registry):**

**Unique Study Reference Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Notice of Withdrawal uploaded to Registry on:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Prescriber’s confirmation of Patient’s withdrawal if received other than by completion and signature of Notice of Withdrawal.**

**Name of Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Unique Study Reference Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

I confirm that the above named Patient has withdrawn from the Study and withdrawn their consent to processing of their personal data.

**Name of Prescriber**

|  |  |
| --- | --- |
| First Name |  |
| Last Name |  |
| Prescriber’s Study Reference ID |  |

**Signature of the Prescriber**

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**For Prescriber’s use (to be completed prior to uploading to Registry)**

**Prescriber’s confirmation of withdrawal uploaded to Registry on:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. EU Directive 2001/83/EC and EU Regulation No. 726/2004 [↑](#footnote-ref-1)
2. Article 12 of Commission Implementing Regulation (EU) No. 520/2012 [↑](#footnote-ref-2)