INFORMATION ABOUT REGISTRATION WITH ZTAS

Zaponex Treatment Access System®

Dear Sir or Madam,

Your physician has informed you of the potential risks and benefits of the use of Zaponex® (clozapine). In addition, you have been informed of the procedures that must be followed associated with the use of Zaponex for the monitoring of your health.

The Zaponex Treatment Access System (ZTAS®) is the patient monitoring service associated with your Zaponex treatment. This service is operated by Leyden Delta BV, the license holder of Zaponex. As per requirement from the UK Health Authorities, all patients treated with Zaponex and their healthcare providers have to participate in and register with the ZTAS.

The ZTAS is in place to ensure the safe use of Zaponex, to monitor your blood counts and to assist your healthcare provider in making medical decisions regarding your Zaponex treatment.

In the interest of providing your health care, complying with legal obligations, and protecting your vital interests the following personal information and your blood samples are required to be collected and processed by the ZTAS monitoring database and service, ***your: Name, NHS number, date of birth, sex, ethnicity, indication for Zaponex use and blood test results.***

Should you experience health problems or side effects during the course of your Zaponex treatment, Leyden Delta will ask your healthcare provider for additional information regarding your health event(s).

Your personal data is processed in accordance with the terms outlined in the ZTAS privacy notice that you have been provided with by your physician and/or which is available at www.ztas.co.uk.

If you do not wish to provide your personal data and register with the ZTAS, your physician shall be unable to initiate treatment of your medical condition with Zaponex (clozapine). The personal information collected from you will be made available to registered users of the ZTAS who need access to the information in support of your Zaponex treatment.

Should you experience abnormal low blood results during the course of your Zaponex treatment which could signify a serious threat to your health, Leyden Delta BV will transfer your data to the Central Non Rechallenge Database (CNRD) in order to prevent a future re-exposure to clozapine treatment, as this may jeopardize your health.

Leyden Delta makes use of service providers for support and maintenance of ZTAS database systems. This means that your personal data is shared with other companies that support the ZTAS service. The ZTAS database is maintained by a service provider in the United States that is required to protect your personal information to recognised standards. Your data and blood samples may be used by Leyden Delta to perform research on Zaponex and for services connected with Zaponex. Data may be published, but you will in no way be identified in such publications. No identifiable data will be used for research purposes. We keep your data for as long as you receive Zaponex treatment and as long as required by law. You have a number of data protection rights (as detailed in the ZTAS privacy notice), including the right to lodge a complaint to any data protection supervisory authority if you have a concern about the processing of your information.

If you experience any health problems or side effects during the course of your Zaponex treatment, other than low blood counts, it is important that you tell your doctor, pharmacist or another member of your care team about it. You can also report side effects directly to the UK health authorities via the Yellow Card Scheme, a national reporting scheme for side effects from medicines. Reports can be at www.mhra.gov.uk/yellowcard or via the MHRA Yellow Card app. By reporting side effects, you can help provide more information on the safety of this medicine.

My healthcare provider has informed me about the treatment of my health condition with Zaponex® (clozapine). I have read the above text and fully understand the nature and purpose of the processing of my personal information and blood samples. My healthcare provider has given me the opportunity to ask questions about Zaponex, the ZTAS monitoring service and the processing of my personal information and blood samples.

Patient

Name S U R N A M E

Date d d - m m - y y y y

Signature

Guardian or legal representative* (if applicable)

Name S U R N A M E

Date d d - m m - y y y y

Signature

* Guardian or legal representative with authority to sign on the patient's behalf.

Statement of the physician or other healthcare provider involved with Zaponex® (clozapine) treatment

I confirm that I have fully explained to the patient the purpose, potential benefits and risks of Zaponex treatment and the need for processing his/her personal information and blood samples for the ZTAS monitoring service.

Name S U R N A M E

Date d d - m m - y y y y

Signature

NOTE: This form should be printed, completed and held with the patient's medical records. It should not be sent to the ZTAS.

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