Please complete this form using **BLACK INK** and **BLOCK LETTERS**

A >>> PATIENT DATA FORM

Zaponex Treatment Access System®

ZTAS®

This form is used to register a patient with the Zaponex Treatment Access System (ZTAS®). Please complete all sections. **INCOMPLETE FORMS WILL NOT BE PROCESSED.** We will use the information provided on this form in accordance with the terms explained in the ZTAS privacy notice which is available from the ZTAS website www.ztas.co.uk. Patients who are treated with Zaponex® (clozapine) must be registered with ZTAS. Additionally, all patients prescribed Zaponex, or another clozapine brand, experiencing a leukopenia and/or neutropenia will be enrolled on a separate database, the Central Non Re-challenge Database (CNRD). The CNRD maintains a central record of these adverse reactions to prevent harmful re-exposure to clozapine. The CNRD is controlled by an independent company, CNRD 2002 Ltd.

This patient will be on ☐ Zaponex Tablets ☐ Zaponex ODT ☐ Other formulation*

* Please specify:

Patient details

NHS number - -

Name SURNAME Initials

FIRSTNAME

Any known aliases for this patient should be recorded in the Comments section.

Date of birth* DD-MM-YYYY

* Clozapine usage in patients under 16 years of age is not recommended and will be considered Off-Licence.

Sex ☐ Male ☐ Female

Ethnicity ☐ Caucasian ☐ African/Caribbean ☐ Asian ☐ Mixed* ☐ Other*

* Please specify:

Indication for use ☐ Treatment Resistant Schizophrenia ☐ Psychotic disorder in Parkinson's disease ☐ Other*

* Please specify: (required for processing)

If the Indication for use is 'Other', the patient is under the age of 16 years, if treatment with clozapine is contra-indicated, OR if the patient is taking any other medications contra-indicated for concomitant use with clozapine, then the use of Zaponex is outside the terms of the Marketing Authorisation and considered "Off-licence". In such situations, use of clozapine is not recommended and the decision to start will be your own responsibility. We request you to also submit an off-licence agreement.

Patient Treatment Status ☐ New ☐ Re-starting with ZTAS* ☐ On-Treatment**

* Please provide ZTAS PIN: Transferring from: ☐ Clozaril ☐ Denzapine

** For On-Treatment patients transferring from the Clozaril or Denzapine brand of clozapine, the monitoring history and 3 most recent blood results will be provided by the transferring monitoring organisation. For On-Treatment patients who have transferred from abroad, the start date of clozapine treatment and the monitoring history must be provided to ZTAS separately; otherwise the patient will be registered as 'New'.

Initial blood result*

Date of Analysis DD-MM-YYYY

White Blood Cell Count ($\times 10^9$/L) .

Eosinophil Count ($\times 10^9$/L) .

Neutrophil Count ($\times 10^9$/L) .

Platelet Count ($\times 10^9$/L) .

* Initial blood result cannot be more than 10 days old to start clozapine. Another sample MUST be taken within 10 days of the initial blood result.

Comments

To be completed by ZTAS

Patient in CNRD : ☐ Yes ☐ No Date: DD-MM-YYYY

Name / Signature NAME SIGNATURE

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Surname patient: S U R N A M E

Responsible Consultant Psychiatrist*

Name N A M E G M C

* Or other relevant specialist in the context of Zaponex® (clozapine) treatment indications, as per SPC.

Treatment Location

Facility name

Postcode Ward

Telephone

Primary (Hospital) Pharmacy

Pharmacy name

Postcode

Zaponex dispensed by another pharmacy in Homecare or dispensing arrangement? ☐ No ☐ Yes*

* If yes, please complete Homecare/dispensing pharmacy

Homecare/dispensing pharmacy

Pharmacy name

Postcode

Blood Testing

Routine Blood Samples will be tested using: ☐ ZTAS Lab ☐ Local Lab ☐ POCT

Local Lab used
e.g. urgent samples

Postcode

Local results must be analysed by a NEQAS (National External Quality Assurance Scheme) or equivalent certified laboratory, details of which must be registered with ZTAS.

Blood Sampling Location (address to send blood sampling kits when ZTAS Lab is used)

Facility name Postcode

Contact person N A M E Telephone

DECLARATION

The information you provide about your patient will be held on the ZTAS database and constitutes their personal and special category personal data. This data will be processed in accordance with applicable data protection legislation in order to monitor your patient's blood results and to assist you and/or other healthcare professionals to make medical decisions regarding your patient's health and to provide you and/or your patients with services connected with ZTAS. Your patient's data and blood samples may be used now or in the future in connection with further research by Leyden Delta (or sponsors whether or not associated with Leyden Delta). Such purposes may or may not be related to Zaponex and/or services connected to it and may also be published (your patient will not be identified in any publications resulting from such research). The information on your patient held on the CNRD will be held for the sole purpose of preventing re-exposure to clozapine and will only be made available to the suppliers of clozapine.

To be completed and signed by Supervising Consultant or ZTAS-registered pharmacist

I certify that, to the best of my knowledge, the information provided is true and accurate. I confirm that I have explained to my patient/guardians that his/her information and blood samples relating to him/her will be processed as described above and in accordance with the terms of the ZTAS privacy notice and I have obtained their consent to undergo treatment.

Name N A M E GMC / GPC / PNI*

* Please circle appropriate.

Date D D - M M - Y Y Y Y Signature S I G N A T U R E

All Adverse Events reported to ZTAS will be escalated to the Leyden Delta Drug Safety Department and follow-up information may be requested of you.

Please send this Form to ZTAS by email on **info@ztas.co.uk**

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