Voraxaze Named Patient Program
Patient Access Form

To request the supply of Voraxaze (the "Product") under the Voraxaze Named Patient Program, this Patient Access Form must be read, completed and signed by the prescribing physician and where necessary the hospital/pharmacist.

customer.services@clinigengroup.com

If your country is not listed below, please use the U.K. contact numbers

	Spain	Italy	France	Belgium	United Kingdom	Germany
Tel.	800 600 217	800 977 669	0800 903406	065 250307	+44 (0)1283494340	069 22223413
Fax	800 600 218	800 977 686	0805 109994	+44 (0)1283494341	+44 (0)1283494341	0800 5892457

Responsibility to the patient

- Informed consent must be obtained from the patient before any treatment is started. The patient should be informed that the Product is not licensed, and is supplied to meet a special need identified by the patient's Physician with the approval, as appropriate, of the national regulatory authority.

- Appropriate consent will be obtained from the patient regarding the processing of any personal data in connection with the Voraxaze Named Patient Program, the communication of such data to third parties (e.g. national regulatory authorities, Clinigen / the Company), the use of the data in reports and studies and any other activities necessary for the proper execution of the Voraxaze Named Patient Program.

- As the prescribing physician you accept personal responsibility for obtaining all necessary consents from the patient, you accept medical responsibility for the use of the Product and all communication with the patient relevant to the request for treatment. Any communication received by Clinigen from the patient will be forwarded to the prescribing physician responsible for the treatment of the patient.

Safety Information Collection and Reporting

BTG and Clinigen will comply with pharmacovigilance legislation which includes the collection and reporting of adverse events (AE's) to all relevant regulatory authorities (where required). To comply with this legislation:

- The prescribing Physician must follow all applicable national pharmacovigilance regulations in relation to named patient/compassionate use of unlicensed product.
- At a minimum, the prescribing Physician must report - directly to BTG and within one business day – any adverse events and/or safety information that the prescribing physician becomes aware of, regardless of whether the prescribing physician suspects a possible causal relationship with the use of the Product or not.
- Where there are no national reporting requirements that are to be fulfilled by the prescribing Physician, but there is a regulatory requirement of the manufacturer to submit reportable adverse events in local language, the prescribing Physician will perform this task upon request from BTG, and will provide the submission date to BTG.
- Details of the AE must be submitted to BTG using the AE Form, a copy of which is attached to this document, which will be provided with each Product delivery. Reporting details, such as BTG entity, fax, telephone, and e-mail information are provided on the AE Form.

Supply of the Product

- Supply of the Product is subject to applicable national regulatory requirements, which may include direct approval from the national regulatory authority and compliance with the requirements described below in the "Declaration by the Prescribing Physician".
- BTG reserve the right to cease supply of the Product if
    - Previously unknown, unexpected and/or serious safety concerns arise.
    - The terms of the Voraxaze Named Patient Program, including the declarations made below, are not adhered to.
    - Required based on changes to local regulatory requirements governing access to unlicensed medicines.

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Declaration by Prescribing Physician:

By signing this Access Form I make the following declarations:

1. I have requested, in accordance with the laws in my country, supply of the Product for the below-mentioned patient who cannot be adequately treated with medications approved or available through clinical trials in my country at this time. I will only prescribe and use this supply for the below-mentioned patient.
2. I acknowledge that this product will be supplied under my direct personal responsibility.
3. I confirm that I have read and understood the product information supplied by Clinigen. I have provided all relevant product information to the patient and will obtain informed consent prior to the first administration of the product.
4. I have informed my patient that this is an unlicensed medicine and that there are risks involved in the use of unlicensed medicines.
5. I confirm that I have asked and obtained consent from the patient to the processing of any personal data in connection with the Voraxaze Named Patient Program, and communication of such data to third parties (e.g. national regulatory authorities, Clinigen / BTG) to the extent necessary for the proper execution.
6. I acknowledge that I am responsible for reporting to BTG any adverse event that may arise in the administration of the product, I will give prompt attention to any request for follow-up and I will submit any reportable adverse events to the relevant national or regional Regulatory Authority, upon request from BTG. I will also supply the submission date to BTG for any submissions I perform. Where there are no national reporting requirements that are to be fulfilled by the prescribing Physician, but there is a regulatory requirement of the manufacturer to submit reportable adverse events in local language, the prescribing Physician will perform this task upon request from BTG, and will provide the submission date to BTG.
7. All medical enquiries should be made to medical.services@btgplc.com
8. I confirm that I have asked and obtained appropriate consent from the patient regarding the processing of any personal data in connection with the Voraxaze Named Patient Program, the communication of such data to third parties (e.g. national regulatory authorities, Clinigen / the Company), the use of the data in reports and studies and any other activities necessary for the proper execution of the Voraxaze Named Patient Program.
9. **I understand that the product is to be stored at 2-8°C at all times.**

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Physician Section: (All fields must be completed)

Prescribing Physician Details

Prescriber Name			
Hospital/ Department			
Telephone			
Email			
Date		**Physician's signature**	

Order Information

Please indicate the treatment requested

Product	**Please indicate the number of Vials Required (1 – 6 vials)**
Voraxaze	_____Vials
If 6 vials please justify here:	

I would like to obtain the Product for the following patient:

Patient Initials*		**Date of Birth***	
Indication			

**This information is required by Clinigen to generate a unique patient identifier for each new patient. The data will be treated as confidential, and not shared with* BTG*, or outside of Clinigen.*

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<u>Pharmacist section:</u> (All fields must be completed)

If your order is placed outside of business hours and you are not able to provide Clinigen Customer Services with a purchase order number this must be provided the next working day.
The purchase order number will be displayed on the invoice for your Finance department.

Delivery Details

Pharmacist			
Email		**Telephone**	
Clinigen Account Number (if known)			
Hospital/ Pharmacy			
Address			
City		**Postal Code**	
Opening hours (for delivery)		**Out of hours contact number (if applicable)**	
Special Delivery Instructions (if applicable)			

Delivery Person Contact Information
If delivery person is not the pharmacist listed above, please provide contact details

Name	
Telephone Number	
Email	