



## ACCESS TO INVESTIGATIONAL MEDICINES PRIOR TO REGULATORY APPROVAL

Alkermes develops innovative new medicines designed to address unmet medical needs of patients in major therapeutic areas. We are focused on creating new medicines that address important, real-world concerns of patients and their families. We currently have investigational treatments in clinical trials for a number of different diseases, as described in the Research and Development, Pipeline section of our website at <http://www.alkermes.com/research-anddevelopment/pipeline>. Alkermes' goal is to efficiently bring safe and effective medicines to all appropriate patients by conducting rigorous clinical trials and obtaining marketing approval by regulatory authorities, including the U.S. Food and Drug Administration (FDA).

Prior to such approval, participation in one of our clinical trials is the optimal way for patients to gain access to our investigational medicines. However, we understand that some patients may not be able to participate in a clinical trial and may seek access to investigational treatments before they are approved.

### General Criteria to Evaluate Requests

If early data from pre-clinical and clinical trials suggest that an investigational treatment can offer benefits for patients facing serious or life-threatening conditions, Alkermes may consider requests to provide access outside of a clinical trial. In reviewing any request, we will consider if:

- The patient to be treated has a serious or immediately life-threatening illness and there is no satisfactory alternative therapy
- It would not be possible for the patient to participate in any ongoing clinical study of the investigational treatment
- There is preliminary evidence to anticipate that any potential benefits from treatment are likely to outweigh any potential risks to the patient
- There is an adequate supply of the investigational treatment to support the clinical trials and the early access request, until and if the drug becomes approved and available by prescription
- Providing the investigational medicine interferes with the timely completion of clinical trials that could lead to marketing approval and thereby could delay its availability to other patients.

## **Making a Request**

Patients interested in obtaining access to an Alkermes investigational therapy must do so via their physician.

Only an appropriately licensed physician may make a request on behalf of a patient. The physician must be qualified and willing to administer and oversee the investigational treatment and comply with Alkermes' safety and monitoring requirements, as well as other regulatory responsibilities.

Contact Information: Physicians should contact Alkermes' Medical Information Center at 1-888-235-8008 or [USMedInfo@alkermes.com](mailto:USMedInfo@alkermes.com). The requesting physician will be required to provide adequate medical history and treatment information for the specific patient.

Anticipated Timing: Receipt of requests will be acknowledged within one business day. All requests will be carefully considered, and a written or oral response will be provided to the requesting physician within five business days of receipt of all documentation required by Alkermes to determine patient eligibility.

Making a request does not guarantee the granting of access to an investigational drug by Alkermes. If approved, the early access supply of investigational medicine may be continued until the drug is approved for use through the local healthcare system, or until, in the opinion of the treating physician, discontinuing treatment is in the best interest of the patient. However, Alkermes cannot guarantee drug supply. Alkermes reserves the right to restrict access or discontinue the early access investigational treatment at any time.

U.S. physicians may find additional information by visiting the U.S. Food and Drug Administration's website [Expanded Access: Information for Physicians](#). Non-U.S. physicians must follow local laws and regulations appropriate for the country originating the request. For information on available clinical trials and early access programs visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).