



Expanded Access Policy



As the therapeutic area leader in non-opioid pain management, Pacira is committed to providing non-opioid pain management options to as many patients as possible and redefining the role of opioids for rescue therapy only. We are also developing innovative interventions to address debilitating conditions such as postoperative atrial fibrillation, chronic pain and spasticity. We take our commitment to the patients we serve very seriously, with shared urgency to develop new treatments as quickly as science and regulatory requirements allow. We believe the best way to fulfill this responsibility is to conduct clinical trials to assess safety and effectiveness and obtain regulatory approval so that our therapies reach as many patients as possible.

Often referred to as “compassionate use,” our Expanded Access Policy (EAP) refers to the use of an investigational product outside of a clinical trial as a potential pathway for a patient to gain access to investigational therapies in certain rare circumstances in which a person has no other available therapies or is not eligible to participate in a current clinical trial. The decision to establish an EAP is dependent on several key factors consistent with the US Food and Drug Administration (FDA) and other regulatory agencies’ guidelines, including:

- The potential patient to be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
- The potential benefit to the patient justifies the potential risks of using the treatment and those potential risks are not unreasonable in the context of the disease or condition to be treated; and
- Providing the investigational treatment for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

Pacira believes that participation in one of our clinical trials is the best way to access our products for investigational treatments. We encourage patients to speak with their physicians regarding participating in clinical trials. As a general policy, Pacira will not provide our investigational therapies until safety and efficacy has been established in our clinical trials.

If you are a patient who is interested in accessing our therapies, please speak with your physician. You may also learn more about ongoing clinical trial(s) by going to www.clinicaltrials.gov and searching for Pacira.

If you are a physician who is interested in learning more about our therapies, or participating in our clinical trials, please submit a request to medinfo@pacira.com.