



Actos Diabetes Drug and Bladder Cancer



Frequently Asked Questions about Actos

Lieff Cabraser Heimann & Bernstein, LLP has successfully represented persons nationwide in individual lawsuits against the manufacturers of prescription drugs with undisclosed and dangerous side effects. We offer our clients the substantial legal and financial resources of a national plaintiffs' law firm while providing each client highly-individualized, attentive representation.

1. What is Actos?

Actos is the registered brand name of the prescription drug pioglitazone, used to treat Type 2 diabetes. Actos is manufactured and marketed by the Japanese-based Takeda Pharmaceutical Company, Ltd. and its U.S. subsidiaries. The U.S. Food and Drug Administration first approved Actos in 1999.

2. Have many patients reported developing bladder cancer after taking Actos?

Yes. The FDA has received over 70 reports of bladder cancer from patients who took Actos. Because these reports are voluntary rather than required, the true number of bladder cancers associated with Actos use is undoubtedly far higher. Published studies show that long-term Actos users have almost double the risk of bladder cancer compared to people who have not used that drug.

3. What actions have health regulators taken concerning Actos?

In June 2011, the U.S. Food and Drug Administration issued a drug Safety Alert Warning that the use of Actos for more than one year may be associated with an increased risk of bladder cancer. At the same time, health authorities in France suspended the use of Actos due to the risk of developing bladder cancer.

The European Medicines Agency (EMA) has required a warning that unpublished results from Takeda's own clinical trials showed a 2.64 times greater risk of bladder cancer with long-term use of Actos, and that the possibility of harm with short-term use could not be excluded.

In April 2012, Health Canada, the Canadian government's drug safety agency, issued a safety warning on Actos. Health Canada reported that diabetes patients prescribed Actos for

Free Case Review

Lieff Cabraser represents persons across America injured by Actos. To contact an experienced injury attorney for a free case evaluation, please call us toll-free at **1-800-541-7358** and ask to speak to attorney Fabrice Vincent or visit www.lieffcabraser.com/Actos.



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over a year had a risk of bladder cancer two times higher than diabetes patients who did not take Actos. Health Canada has stated that even the short-term use of Actos may increase the risk of bladder cancer.

4. Why does Lief Cabraser contend that Takeda is legally responsible for patients prescribed Actos developing bladder cancer?

Manufacturers of prescription drugs have a duty to patients to produce safe products and to warn patients and their doctors of any adverse health effects.

Lawsuits filed against Takeda allege that Actos is a defective and unreasonably dangerous prescription drug. The complaints allege that Takeda sold Actos without adequate warnings about the increased risk of serious injuries and, specifically, failed to warn doctors and patients that Actos use may double the risk for diabetes patients of developing bladder cancer.

5. What evidence is there that Takeda knew of a link between Actos and bladder cancer and yet failed to warn patients and physicians of the risk?

Injured diabetes patients who took Actos have filed suit against Takeda charging that prior to the drug's introduction to the market

in 1999, the company possessed studies on laboratory rats showing an increased risk of developing bladder cancer when the animals were given Actos. Takeda claimed that these results were unique to rats and not relevant to humans, but

a careful drug company would not have made that assumption, which is contradicted by the studies showing higher bladder cancer incidence in people who have taken the drug.

Upon approval in 1999, the FDA directed Takeda to undertake a post-market study on the safety and effectiveness of Actos. However, Takeda allegedly delayed initiating the study until 2003 and designed the study as a 10-year trial. Because of this study design, the final results will not be available until after the recent expiration of Takeda's exclusive patent on Actos. However, interim results published in 2011 did show increased risk of bladder cancer, which led to the FDA directing that a new warning appear on the label.

In 2005, the results of a Takeda study intended to show cardiovascular benefits of Actos were published. This study found 14 bladder cancers among patients in the Actos group, compared to 5 bladder cancers in the group that did not take Actos. Takeda again denied that Actos was to blame for the higher rate of cancer.

To this day, the warning label on Actos states; "There are too few events of bladder cancer to establish causality."

6. I believe I suffered an injury due to taking Actos. How quickly must I hire an attorney?

If you or a loved one just recently learned of a bladder cancer diagnosis, you should not feel pressured to make an immediate decision about hiring counsel. Focusing on restoring your health or mourning the loss of loved ones should take precedence over liabil-



ity issues at this difficult time.

However, keep in mind that each state imposes a deadline for filing lawsuits. This deadline is known as the statute of limitations, which in certain states is one year from the date you learned of the injury that Actos may have caused. There might also be other deadlines imposed by state law that may require action sooner than one year.

7. Will I have to pay a fee for your review of my case?

No. We do not charge to review your case. If we decide we can represent you and you wish to retain Lieff Cabraser as your law firm, we will discuss our contingency fees (calculated as a percentage of the recovery we obtain) and then provide a written contract to be agreed upon.

8. What are my legal rights after an injury?

In most states, an injured person may file a case for negligence, failure to warn of known dangers, design defects, and other legal claims for compensation. In wrongful death cases, most states provide that the decedent's spouse and children are entitled to sue for damages. If there is no spouse, then a child (or guardian of a child) may sue. If there is neither a spouse nor child, then the decedent's parents are entitled to sue. After the parents, siblings are next in line under the law.

9. How long will a lawsuit take?

We cannot give any guarantees as to when your case will be resolved. First, we must undertake a thorough investi-

gation of the facts of your case. In some instances, a case will settle to our client's satisfaction shortly after it is filed, or perhaps even before filing.

In most cases of this nature, however, defendants typically deny that their product caused any harm. As a result, the injured patient must file a lawsuit, and the litigation process can be lengthy. Rest assured, Lieff Cabraser works as swiftly and efficiently as possible to obtain the maximum compensation for our clients and to bring each case to a successful conclusion. We do not charge our clients hourly fees and earn no compensation for ourselves until you receive your recovery.

10. How do I select an attorney to represent me?

You should seek a lawyer who has substantial experience in successfully handling similar cases. It is important to not only verify the reputation and experience of the law firm as a whole, but to be sure that your case will be handled by individuals with appropriate experience.

In suits involving dangerous prescription drugs, a case can be expensive to litigate and typically requires the hiring of experts. You should choose a law firm with substantial financial resources to conduct the case through trial and appeal if necessary.

11. What recovery will I receive?

In most jurisdictions, if you suffered a personal injury and the defendant is found liable, the defendant is responsible for paying for your medical care, both past and expected, your past and future lost earnings, and an amount to

Our Promise to You

- Our injury lawyers have successfully represented thousands of clients across America in personal injury cases involving prescription drugs.
- We provide each client with high-level individualized representation.
- We employ a team of dedicated researchers, legal assistants, law clerks, and multiple registered nurses to assist our clients and lawyers.
- There is no charge or obligation for our review of your injury lawsuit.
- We have retained product safety and medical experts nationwide to assist our clients with their claims.

Contact an Actos Personal Injury Attorney

If you or a loved one have been prescribed Actos and developed bladder cancer, please visit us at: www.lieffcabraser.com/Actos or call us toll-free at 1-800-541-7358 and ask to speak to attorney Fabrice Vincent. Our personal injury attorneys and legal nurse consultants will promptly review your case for no charge and with no obligation on your part.

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compensate you for pain and suffering. Your spouse may also be entitled to an award.

If a loved one died, the recovery usually is based on the amount of economic support and services that you lost, plus, in some jurisdictions, an amount designed to compensate for your grief, mental anguish, and loss of association. We have economists who specialize in evaluating these injuries and calculating the appropriate monetary compensation for your loss.

If the conduct that caused the injury was egregious, you may also be entitled to an award of punitive damages in certain states.

12. How will you handle my case?

As our client, you possess the direction and control over the case. For example, if Takeda should make an offer to settle the case, we will promptly inform you. We will advise whether or not you should accept the offer based on the law and facts of your case. The decision, however, will be yours alone to make.

If you agree to retain our firm, we will prosecute your case as a personal injury lawsuit. You will be assigned an individual attorney who will keep you regularly informed as to the status of your case. At the same time, our attorneys work as a team, sharing evidence and following a strategic plan for the Actos litigation. In addition, we have multiple nurses, legal assistants, scientific analysts, and case clerks on

staff to assist our attorneys, helping to gather the evidence necessary to prove your case and for you to obtain the full compensation you are entitled to under the law.

13. Why don't I just contact Takeda and try to work out a settlement with the company?

It is usually inadvisable to try to resolve a serious injury or wrongful death case on your own. An injury may involve multiple parties and questions concerning what happened, who was legally responsible, and how the matter should be resolved. At Lieff Cabraser, our attorneys are trained and have the expertise to evaluate your case and advise you of your rights. Without an experienced attorney working on your behalf, you may never know the true value of your case or gather the evidence to show Takeda's alleged misconduct.

It is important to understand that corporations and their insurers employ the services of expert lawyers who seek to avoid responsibility or at least to minimize the payments that will be made to victims and families. In contrast, it is our duty and our job to identify all responsible parties, bring a legal action on your behalf to maximize the compensation available under the law, and obtain justice for you.

Disclaimer: This document is not intended to provide medical advice. Any questions specific to your health should be posed to your physician. The hiring of an attorney is an important decision that should not be based solely upon promotional materials. Before you decide to retain us, feel free to ask us any questions you may have concerning our qualifications and experience. Prior results do not guarantee a similar outcome.