

# Parker & Waichman, LLP Attorneys at Law

## Paxil Information Guide



**Manufacturer:**  
GlaxoSmithKline

**Generic Name:**  
Paroxetine HCl

**Date Approved:**  
December 29, 1992

**Status:**  
On the market

**Approved Uses:**  
Depression

**Serious Side Effects:**  
Suicide  
Suicidal ideation  
Violence  
Birth Injuries

**Related Topics**  
Celexa  
Cymbalta  
Effexor  
Lexapro  
Luvox  
Prozac  
Remeron  
Serzone  
Wellbutrin  
Zoloft  
Birth Injuries  
Antidepressants  
Defective Drugs  
Malpractice

### The Case Against Paxil:

Paxil (generic name: paroxetine hci) has been linked with suicide, suicidal ideation and violence in children and teenagers. Paxil has also been associated with terrible withdrawal symptoms. Paxil is most commonly used to treat depression but is also prescribed to treat anxiety, panic, obsessive-compulsive disorder, and post traumatic stress disorder.

The FDA has recently issued a warning for Paxil, stating that the drug can cause suicide and violence in children and teenagers. This follows a report issued by Britain's Department of Health which said that evidence provided by the drug company, from nine studies based on more than 1,000 youngsters, shows there is an increase in the rate of self harm and potentially suicidal behavior in those under 18 taking Paxil.

British health regulators have recently issued a warning for Paxil, stating that the drug can cause suicide and violence in children and teenagers. Following their British counterparts, Irish health officials issued a warning for Paxil in Ireland and the FDA has said it will investigate the drug further.

Britain's Department of Health said the evidence provided by the drug company, from nine studies based on more than 1,000 youngsters, shows there is an increase in the rate of self-harm and potentially suicidal behavior in those under 18 taking Paxil. The British regulators wrote in a statement "It has become clear that the benefits of Seroxat in children for the treatment of depressive illness do not outweigh these risks."

The FDA is strengthening its warning for the antidepressant Paxil because it may be associated with birth defects, citing a new study that found increased risk of fetuses developing heart defects.

The FDA asked manufacturer GlaxoSmithKline to reclassify the drug, which goes by the generic name paroxetine, as a "Category D" drug for pregnant women. The classification means that studies in pregnant women have shown a risk to the fetus. Two studies of pregnant women taking Paxil during their first trimester have shown their babies have heart defects one and a half to two times a greater rate than the norm, the FDA said.

The FDA is advising doctors not to prescribe Paxil to women in their first three months of pregnancy or people who are planning to become pregnant, unless there are no other options.

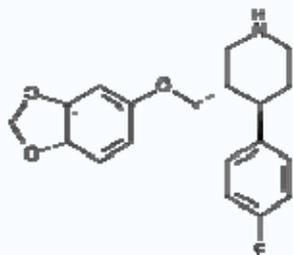
Additionally, Paxil has long been associated with difficult withdrawal side effects, leaving patients virtually addicted to the drug. Recently, The British drug agency required Glaxo to remove a statement on its patient label saying that the drug was not addictive.

It is estimated that almost 17 million people worldwide have been treated with Paxil.

If you or a loved one has been injured by Paxil, Parker & Waichman, LLP will evaluate your case for free. [Click here for a free case evaluation.](#)

## Paxil (Paroxetine HCl)

From Wikipedia, the free encyclopedia.



### Chemical Composition

Paroxetine or paroxetine hydrochloride (sold under the trade names Paxil® in the United States and Canada, Seroxat® in the UK and China, Aropax® in Australia and New Zealand, Deroxat in Switzerland and in France) is an antidepressant of the selective serotonin reuptake inhibitor (SSRI) type. It was released onto the market in 1992 by the pharmaceutical company GlaxoSmithKline and has since become one of the most prescribed antidepressants on the market. It is the second most prescribed antidepressant in the UK. It is now the subject of a fraud case in the United States due to allegations that GlaxoSmithKline suppressed research indicating that the drug caused young people to become suicidal.

Like some other antidepressants, it is also prescribed in the treatment of anxiety disorders and obsessive-compulsive disorder (OCD). It was the first (and as of 2002, the only) antidepressant formally approved in the United States for the treatment of social anxiety disorder, causing it to be sometimes referred to (although inaccurately) as an anti-shyness drug.

### **Addictive potential**

The manufacturers claim it is impossible to become addicted to paroxetine. Other campaigners disagree. The medical community generally considers that withdrawal symptoms are not enough to regard a drug as addictive; it has to leave the user needing more and more in order to gain the same desired effect. Despite the frequency of 'Prozac wear-out', where an antidepressant becomes less effective over time, and that tolerance to side-effects over the first few weeks of treatment is acknowledged, it is still often claimed that tolerance does not occur. Note, however, that addiction is generally also an extremely debated issue, although no drug is generally considered to be addictive that does not have both withdrawal symptoms and tolerance.

## Side effects

Concerns are growing about the side effects of Paxil.

Recent studies have found that the drug is relatively ineffective in children, and suggested that they are prone to becoming suicidal in the early stages of treatment. Some psychologists believe that this is due to the way the drug begins to work in many patients. The first effect most people notice is a decrease in the lethargy and amotivation they experienced during their depression. This effect happens *before* the depression itself improves, so children may end up with enough "energy" and motivation to act on suicidal tendencies they may have already had.

It is also important to note many people who are prescribed Paxil are suicidal to begin with. However most studies have compared suicide rates in patients using Paroxetine against a control group of depressed individuals not being treated with paroxetine and the paroxetine group was reported to be twice as likely to commit suicide.

Although the manufacturers say there is no reliable clinical evidence that the drug can cause violence or aggression, a wrongful death suit was filed against GlaxoSmithKline in June 2001 by the surviving family of Donald Schell, a Wyoming man who had killed his wife, daughter and grandchild after two days on the drug. During the investigation of the clinical records, it was reported that, although paroxetine is safe and effective most of the time, in a minority of cases the drug can cause unpredictable side effects such as wild mood swings or suicidal thoughts. The jury ultimately awarded damages of \$8 million against GlaxoSmithKline.

In June 2004 New York attorney general Eliot Spitzer began civil proceedings against GlaxoSmithKline over allegations that the company had suppressed five internal studies between 1998 and 2002 on the effects of the drug on both children and adults which suggested that, at best, the drug had little more effect than a placebo and at worst induced suicidal tendencies in its users. The company responded shortly later by making the results of the studies publicly available.

In March 2005, the United States Food and Drug Administration ordered the seizure of millions of tablets of Paxil after 3 years of GlaxoSmithKline's unresolved manufacturing problems. These problems involved Paxil CR, a time-release version of the drug. Some capsules were found to break in two, potentially resulting in the user taking only the active element of the drug without the time-release portion, or vice versa.

In September 2005 the Therapeutic Goods Administration (TGA) of Australia issued a warning about the potential for increased birth defects in the babies of pregnant women taking the anti-depressant Paroxetine. Early results from pharmaceutical giant GlaxoSmithKline suggest an association between taking the drug in the first three months of pregnancy and birth defects. The risk of cardiovascular defects may double from 1 to 2 per cent in babies of women taking Paroxetine. A recent Dutch study suggests a 60 per cent increase in defects. The TGA is urging women not to suddenly stop taking the SSRI

as withdrawal may cause harmful side effects. In December 2005, the United States Food and Drug Administration issued a similar public health advisory [1]. In this report, the FDA has decided to change paroxetine from pregnancy category C to D, indicating a higher degree of caution is warranted when using paroxetine in pregnant women.

### **Common side effects include:**

drowsiness  
nausea  
anxiety  
dry mouth  
constipation  
diarrhea  
decreased or eliminated sexual desire  
delayed or eliminated orgasm  
rash  
restlessness or akathisia  
itch  
sodium depletion  
changes in urination  
changes in appetite

Individuals experiencing any of the following symptoms should contact their doctor immediately:

jaw, neck, and back muscle spasms  
fever, chills, sore throat, or flu-like symptoms  
yellowing of the skin or eyes  
black, tarry stools (this can indicate upper GI bleeding)

### **Persistent sexual side effects**

For some people the sexual side effects of Paxil and other SSRIs can persist for a very long time after quitting the drugs, sometimes for many years. For some unfortunate people, the [Sexual dysfunction](#) may even be permanent (see link below). Indeed, the SSRI Prozac (fluoxetine) was recently classified as a reproductive and developmental toxin by the Center for the Evaluation of Risks to Human Reproduction (CERHR), an expert panel at the National Institute of Environmental Health Sciences at the National Institutes of Health.

### **Withdrawal symptoms**

There are personal and anecdotal accounts of withdrawal symptoms from paroxetine. This is referred to as 'discontinuation syndrome' and refers to problems which result upon immediate discontinuation of the drug.

Initially, the response of drug regulators (based eg on a report by Price et al, 1995) were that withdrawal symptoms (or 'discontinuation reactions' as SKB/GSK insisted) were

generally mild and short-lived, an opinion that has been replaced by mounting concern. Now, it seems about a third of users have problems stopping paroxetine, and the symptoms are strikingly similar ('electric shock' paraesthesia, dizziness, flu-like symptoms, auditory hallucinations, etc). It is clear that what is under discussion is not psychological dependence.

Withdrawal symptom severity varies from individual to individual and can last from months to years. The most common and successful technique for protection against a difficult withdrawal experience is to lower dosage levels gradually over time. Symptoms arising from a dose change often don't fully appear for several weeks. Since paroxetine has a much shorter half life than other SSRIs like Prozac, people have occasionally sought to buffer their withdrawal plan with a liquid form of Prozac. In liquid form, dose diminishment of 1m.g. are easy to achieve.

Suicidal ideation is a frequently reported experience in those withdrawing from SSRIs like paroxetine. Never seek to withdraw from paroxetine or any other SSRI without supervision.

## Chemistry

Paroxetine is chemically identified as (*Immediate-Release Tablets / Oral Suspension*:) (-)-*trans*-4*R*-(4-fluorophenyl)-3*S*-[(3,4-methylenedioxyphenoxy) methyl]piperidine hydrochloride hemihydrate, or (*Controlled-Release Tablets*:) (-)-(3*S*,4*R*)-4-[(*p*-fluorophenyl)-3-[(3,4-methylenedioxy)phenoxy]methyl] piperidine hydrochloride hemihydrate. Its empirical formula is C<sub>19</sub>H<sub>20</sub>FNO<sub>3</sub>, with a molecular weight of 374.8 (329.3703 as free base).

Paroxetine hydrochloride is an odorless, off-white powder, having a melting point range of 120° to 138°C and a solubility of 5.4 mg/mL in water.

## Pharmacology

Paroxetine is a potent and selective serotonin (5-hydroxytryptamine, 5-HT) reuptake inhibitor (SSRI). This activity of the drug on brain neurons is thought to be responsible for its antidepressant effects.

Paroxetine is a phenylpiperidine derivative which is chemically unrelated to the tricyclic or tetracyclic antidepressants. In receptor binding studies, paroxetine did not exhibit significant affinity for the adrenergic (alpha(1), alpha(2), beta), dopaminergic, serotonergic (5HT(1), 5HT(2)), or histaminergic receptors of rat brain membrane. A weak affinity for the muscarinic acetylcholine receptor was evident. The predominant metabolites of paroxetine are essentially inactive as 5-HT reuptake inhibitors.

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