

# Fioricet

## What is Fioricet?

Fioricet contains a combination of acetaminophen, butalbital, and caffeine. Acetaminophen is a pain reliever and fever reducer.

Butalbital is in a group of drugs called barbiturates. It relaxes muscle contractions involved in a tension headache.

Caffeine is a central nervous system stimulant. It relaxes muscle contractions in blood vessels to improve blood flow.

Fioricet is used to treat tension headaches that are caused by muscle contractions. While Fioricet can be an effective and life-changing medication for people suffering from tension headaches, there is also the risk of Fioricet abuse or addiction.

It's important to consider the possible side effects and risks of using Fioricet to determine if this drug is right for you.

Fioricet may also be used for purposes not listed in this medication guide.

# Fioricet

**What to Buy Fioricet Online ?**

**180 Tab Fioricet - \$239**

**180 Tab Gabapentin - \$199**

[usahealthstore.com](http://usahealthstore.com)

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**BUY FIORICET OR BUY  
GABAPENTIN COD**

**Click to Buy**

# Fioricet

Fioricet is supplied in hard-gelatin capsule form for oral administration. Each capsule contains the following active ingredients:

|                         |        |
|-------------------------|--------|
| Butalbital, USP.....    | 50 mg  |
| Acetaminophen, USP..... | 300 mg |
| Caffeine, USP.....      | 40 mg  |

Inactive Ingredients: sodium lauryl sulfate, talc, microcrystalline cellulose, stearic acid, FD&C red # 40, titanium dioxide, FD&C blue # 1, FD&C yellow # 6, gelatin.

Butalbital (5-allyl-5-isobutylbarbituric acid), is a short to intermediate-acting barbiturate.

Acetaminophen (4'-hydroxyacetanilide), is a non-opiate, non-salicylate analgesic and antipyretic.

Caffeine (1,3,7-trimethylxanthine), is a central nervous system stimulant.

# Fioricet

Fioricet containing 50 mg butalbital, 300 mg acetaminophen, and 40 mg caffeine.

**NDC 52544-080-01**

**Fioricet<sup>®</sup>**  
*(butalbital, acetaminophen,  
and caffeine capsules, USP)*

**Each Capsule Contains:**  
Butalbital, USP..... 50 mg  
**Warning:** May be habit-forming  
Acetaminophen, USP ..... 300 mg  
Caffeine, USP..... 40 mg

**DOSAGE AND ADMINISTRATION:**  
**Usual Adult Dosage:** 1 or 2 capsules every 4 hours. Total daily dose should not exceed 6 capsules. See package insert for additional prescribing information.

**Store and Dispense:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Dispense in a tight container.


**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

**Manufactured By:**  
Nexgen Pharma, Inc.  
Irvine, CA 92606  
7029-0100-WB-EC

**Distributed By:**  
Actavis Pharma, Inc.  
Parsippany, NJ 07054 USA  
Rev. 02/2020

**Non Varnish/Coding Area**

Lift Here



3 52544-080-01 8

**Actavis** 100 Capsules **Rx** only

# Fioricet Pictures





# Fioricet Important information

You should not use Fioricet if you have porphyria, or if you have recently used alcohol, sedatives, tranquilizers, or other narcotic medications.

Do not use Fioricet if you have taken a MAO inhibitor in the past 14 days. A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, phenelzine, rasagiline, selegiline, and tranylcypromine.

Do not take more Fioricet than is recommended. An overdose of acetaminophen can damage your liver or cause death. Call your doctor at once if you have nausea, pain in your upper stomach, itching, loss of appetite, dark urine, clay-colored stools, or jaundice (yellowing of your skin or eyes).

In rare cases, acetaminophen may cause a severe skin reaction. Stop taking Fioricet and call your doctor right away if you have skin redness or a rash that spreads and causes blistering and peeling.

Butalbital belongs to the group of medicines called barbiturates. Barbiturates act in the central nervous system (CNS) to produce their effects.

Acetaminophen is used to relieve pain and reduce fever in patients. It does not become habit-forming when taken for a long time. But acetaminophen may cause other unwanted effects when taken in large doses, including liver damage.

# Fioricet - Before Taking

You should not use Fioricet if you are allergic to acetaminophen, butalbital, or caffeine, if you have porphyria, or if you have recently used alcohol, sedatives, tranquilizers, or other narcotic medications.

To make sure Fioricet is safe for you, tell your doctor if you have:

- liver disease, cirrhosis, a history of alcoholism or drug addiction, or if you drink more than 3 alcoholic beverages per day;
- kidney disease;
- asthma, sleep apnea, or other breathing disorder;
- stomach ulcer or bleeding;
- a history of skin rash caused by any medication;
- a history of mental illness or suicidal thoughts; or
- if you use medicine to prevent blood clots.

# Fioricet - Pregnancy

## **Teratogenic Effects**

Pregnancy Category C: Animal reproduction studies have not been conducted with this combination product. It is also not known whether butalbital, acetaminophen, and caffeine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should be given to a pregnant woman only when clearly needed.

## **Nonteratogenic Effects**

Withdrawal seizures were reported in a two-day-old male infant whose mother had taken a butalbital-containing drug during the last two months of pregnancy. Butalbital was found in the infant's serum. The infant was given phenobarbital 5 mg/kg, which was tapered without further seizure or other withdrawal symptoms.



# Fioricet - Nursing Mothers

Caffeine, barbiturates, and acetaminophen are excreted in breast milk in small amounts, but the significance of their effects on nursing infants is not known. Because of potential for serious adverse reactions in nursing infants from butalbital, acetaminophen, and caffeine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## **Pediatric Use**

Safety and effectiveness in pediatric patients below the age of 12 have not been established.

## **Geriatric Use**

Clinical studies of butalbital, acetaminophen, and caffeine capsules did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Butalbital is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

# Fioricet - How should I take ?

Take Fioricet exactly as prescribed. Follow all directions on your prescription label. Do not take more of this medication than recommended. An overdose can damage your liver or cause death. Tell your doctor if the medicine seems to stop working as well in relieving your pain.

Butalbital may be habit-forming. Never share Fioricet with another person, especially someone with a history of drug abuse or addiction. Keep the medication in a place where others cannot get to it. Selling or giving away Fioricet is against the law.

Take Fioricet with food or milk if it upsets your stomach.

Store Fioricet at room temperature away from moisture and heat.

Keep track of the amount of medicine used from each new bottle. Butalbital is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

**One or 2 tablets every 4 hours as needed. Total daily dosage should not exceed 6 tablets.**

**Extended and repeated use of Fioricet is not recommended because of the potential for physical dependence.**

# Fioricet - What should I avoid ?

This medication can cause side effects that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert.

Avoid drinking alcohol. It may increase your risk of liver damage while taking acetaminophen.

Ask a doctor or pharmacist before using any other cold, allergy, pain, or sleep medication. Acetaminophen (sometimes abbreviated as APAP) is contained in many combination medicines. Taking certain products together can cause you to get too much acetaminophen which can lead to a fatal overdose. Check the label to see if a medicine contains acetaminophen or APAP.

While you are taking this medication, avoid taking diet pills, caffeine pills, or other stimulants (such as ADHD medications) without your doctor's advice.

# Fioricet – Adverse Reaction

## **Frequently Observed**

The most frequently reported adverse reactions are drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, and intoxicated feeling.

## **Infrequently Observed**

All adverse events tabulated below are classified as infrequent.

Central Nervous System: headache, shaky feeling, tingling, agitation, fainting, fatigue, heavy eyelids, high energy, hot spells, numbness, sluggishness, seizure. Mental confusion, excitement, or depression can also occur due to intolerance, particularly in elderly or debilitated patients, or due to overdose of butalbital.

Autonomic Nervous System: dry mouth, hyperhidrosis.

Gastrointestinal: difficulty swallowing, heartburn, flatulence, constipation.

Cardiovascular: tachycardia.

# Fioricet – Adverse Reaction

Musculoskeletal: leg pain, muscle fatigue.

Genitourinary: diuresis.

Miscellaneous: pruritus, fever, earache, nasal congestion, tinnitus, euphoria, allergic reactions.

Several cases of dermatological reactions, including toxic epidermal necrolysis and erythema multiforme, have been reported.

The following adverse drug events may be borne in mind as potential effects of the components of this product. Potential effects of high dosage are listed in the OVERDOSAGE section.

Acetaminophen: allergic reactions, rash, thrombocytopenia, agranulocytosis.

Caffeine: cardiac stimulation, irritability, tremor, dependence, nephrotoxicity, hyperglycemia.



# Fioricet – Abuse and Dependence

## **Butalbital**

Barbiturates may be habit-forming: Tolerance, psychological dependence, and physical dependence may occur especially following prolonged use of high doses of barbiturates. The average daily dose for the barbiturate addict is usually about 1500 mg.

As tolerance to barbiturates develops, the amount needed to maintain the same level of intoxication increases; tolerance to a fatal dosage, however, does not increase more than two-fold.

As this occurs, the margin between an intoxication dosage and fatal dosage becomes smaller. The lethal dose of a barbiturate is far less if alcohol is also ingested. Major withdrawal symptoms (convulsions and delirium) may occur within 16 hours and last up to 5 days after abrupt cessation of these drugs.

Intensity of withdrawal symptoms gradually declines over a period of approximately 15 days. Treatment of barbiturate dependence consists of cautious and gradual withdrawal of the drug. Barbiturate-dependent patients can be withdrawn by using a number of different withdrawal regimens.

One method involves initiating treatment at the patient's regular dosage level and gradually decreasing the daily dosage as tolerated by the patient.

# Fioricet – Overdose

Following an acute overdosage of butalbital, acetaminophen, and caffeine, toxicity may result from the barbiturate or the acetaminophen. Toxicity due to caffeine is less likely, due to the relatively small amounts in this formulation.

## **Signs and Symptoms**

Toxicity from barbiturate poisoning includes drowsiness, confusion, and coma; respiratory depression; hypotension; and hypovolemic shock.

In acetaminophen overdosage: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and coagulation defects may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis, and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

Acute caffeine poisoning may cause insomnia, restlessness, tremor, and delirium, tachycardia and extrasystoles.

## **In case of emergency/overdose**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

# Fioricet – Overdose Treatment

A single or multiple drug overdose with this combination product is a potentially lethal polydrug overdose, and consultation with a regional poison control center is recommended. Immediate treatment includes support of cardiorespiratory function and measures to reduce drug absorption.

Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Assisted or controlled ventilation should also be considered.

Gastric decontamination with activated charcoal should be administered just prior to N-acetylcysteine (NAC) to decrease systemic absorption if acetaminophen ingestion is known or suspected to have occurred within a few hours of presentation. Serum acetaminophen levels should be obtained immediately if the patient presents 4 hours or more after ingestion to assess potential risk of hepatotoxicity; acetaminophen levels drawn less than 4 hours post-ingestion may be misleading. To obtain the best possible outcome, NAC should be administered as soon as possible where impending or evolving liver injury is suspected.

Intravenous NAC may be administered when circumstances preclude oral administration.

Vigorous supportive therapy is required in severe intoxication. Procedures to limit the continuing absorption of the drug must be readily performed since the hepatic injury is dose dependent and occurs early in the course of intoxication.

# Fioricet – Brand Names

|           |            |              |
|-----------|------------|--------------|
| Americet® | Fioricet®  | Pacaps®      |
| Anolor®   | Fiorpap®   | Pharmagesic® |
| Anoquan®  | G-1®       | Quala Cet®   |
| Arcet®    | Ide-cet®   | Repan®       |
| Dolgic®   | Isocet®    | Tenake®      |
| Dolmar®   | Margesic®  | Tencet®      |
| Endolor®  | Medigesic® | Triad®       |
| Esgic®    | Minotal®   | Two-Dyne®    |
| Ezol®     | Mygracet®  | Zebutal®     |

# Fioricet – Storage and Disposal

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature, away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p>) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach.

<http://www.upandaway.org>



# Fioricet – Drug Interaction

Fioricet contains Butalbital, Acetaminophen, and caffeine. A lot of other pain relievers contain Butalbital, Acetaminophen, and caffeine too.

I can only list some common over the counter medicines that contain Acetaminophen: Actifed, Alka-Seltzer, Plus Liquid Gels, Anacin, Cepacol, Contac, Coricidin, Dayquil, Dimetapp, Dristan, Excedrin, FEVERALL ...

Some prescriptions that contain acetaminophen are: Ultracet, Fioricet, Oxycodone, Endocet, Tylox ...

You also must know what drugs contain Butalbital: Bupap, Phrenilin, Tencon, Cephadyn; Fioricet, Esgic, Esgic-Plus; Fioricet with Codeine, Fioricet with Codeine, Phrenilin with Caffeine and Codeine; Axotal; Fiorinal, Butalbital Compound, Farbital, Idenal; Fiorinal with Codeine, Fiorinal with Codeine III, Ascomp with Codeine, Fiorinal with Codeine.

For More Fioricet Interaction, please check following links:

<https://fioricetbutalbital.com/fioricet-drug-interaction/>