

PART III: CONSUMER INFORMATION

^NFIORINAL*-C 1/4, 1/2 (acetylsalicylic acid-caffeine-codeine-butalbital)

This leaflet is part III of a three-part "Product Monograph" published when FIORINAL*-C was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FIORINAL*-C. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

FIORINAL*-C, is used for the relief of tension-type headache.

FIORINAL*-C is recommended for adults 18 years and older.

What it does:

FIORINAL*-C consists of acetylsalicylic acid (ASA), caffeine, codeine and butalbital. ASA reduces pain, fever and inflammation. Caffeine is a mild stimulant which may enhance pain-relieving effects. Codeine is a narcotic used to relieve pain and butalbital is a sedative that causes relaxation. This combination is used to relieve tension-type headaches.

When it should not be used:

You should NOT take FIORINAL*-C if you:

- have a history of allergic reactions to ASA, caffeine, codeine, butalbital or any other components of the FIORINAL*-C capsules (see "What the nonmedicinal ingredients are")
- have a condition that predisposes to bleeding such as hemophilia, hyprothrombinemia, von Willebrand's disease, thrombocytopenia, thrombasthenia and other ill-defined hereditary platelet dysfunctions, severe vitamin K deficiency and severe liver damage
- have nasal polyps, allergic reaction or bronchospastic reactivity to ASA or other nonsteroidal anti-inflammatory drugs (NSAIDs)
- have a condition where the small bowel does not work properly (paralytic ileus)
- have stomach ulcers or other serious stomach or bowel sores
- have a disease called porphyria
- have a history of drug abuse or drug overdose due to alcohol, sleeping pills, drugs to treat pain or any other prescription or illegal drugs
- have severe asthma, severe lung problems or other breathing difficulties
- have pneumonia (a lung infection)
- are pregnant, in labour or breast-feeding.

FIORINAL*-C is not recommended in children less than 18 years old.

What the medicinal ingredients are:

ASA (acetylsalicylic acid), caffeine, codeine and butalbital.

What the nonmedicinal ingredients are:

FIORINAL*-C capsules contain the following non-medicinal ingredients: cornstarch, microcrystalline cellulose, stearic acid and talc.

What dosage forms it comes in:

FIORINAL*-C 1/4 capsules contain 330 mg ASA, 40 mg caffeine, 15 mg codeine phosphate and 50 mg butalbital.

FIORINAL*-C 1/2 capsules contain 330 mg ASA, 40 mg caffeine, 30 mg codeine phosphate and 50 mg butalbital.

WARNINGS AND PRECAUTIONS

Keep FIORINAL*-C out of the reach of children. You should not give FIORINAL*-C to anyone as inappropriate use may have severe medical consequences.

BEFORE you use FIORINAL*-C talk to your doctor or pharmacist if you:

- are allergic to ASA as it can cause anaphylactic shock and other severe allergic reactions
- have nasal polyps or asthma
- have a history of blocked bowels, stomach ulcers, sores in your stomach or bowel or any other serious stomach problems
- have a history of bleeding
- will be having surgery
- have severe liver or kidney disease
- have a blood clotting disorder or are taking blood thinners
- have recently suffered a head injury or elevated pressure in your brain
- have problems with your thyroid gland
- have narrowing of the urethra caused by injury or disease
- have Addison's disease
- have an enlarged prostate gland
- have softening or weakening of bones or osteoporosis
- have any allergies to any medicines, food, dyes or preservatives
- have the flu, or chickenpox
- are pregnant, may become pregnant, in labour or breastfeeding
- have reacted strongly to other codeine-containing drugs in the past (i.e. got sleepy, confused and/or had trouble breathing) even when taking the dose recommended by your doctor.

FIORINAL*-C is not recommended for **anyone** who has or is at risk for breathing problems such as:

- lung infections, or respiratory conditions
- neuromuscular disorders
- severe heart problems
- recent multiple traumas or extensive surgical procedures

Some people metabolize codeine at a much faster rate than the general population, which may lead to accidental overdose, if this should happen to you, seek help immediately (see PROPER USE OF THIS MEDICINE: Overdose, below for symptoms of overdose and what to do if it happens). If you know that you metabolize codeine rapidly, tell your doctor BEFORE starting this medication.

FIORINAL*-C is a controlled medication. Butalbital and codeine are both habit-forming (tolerance, mental and physical dependence) and potentially abusable. Some patients, particularly those who have abused drugs in the past, may have a higher risk of abusing or developing an addiction while taking barbiturate- or opioid-containing products, such as FIORINAL*-C. Physical dependence may lead to withdrawal side effects when you stop taking this medicine. Continuous daily use of FIORINAL*-C should be avoided as medication overuse (rebound) headaches may result in addition to the tolerance and dependence risks. Patients should take FIORINAL*-C only for as long as it is prescribed, in the amounts prescribed, and no more frequently than prescribed.

While there are important differences between physical dependence and addiction, each is a reason for close medical supervision and honest discussions with your doctor. If you have questions or concerns about abuse, addiction or physical dependence, please tell your doctor.

ASA may increase the risk of Reye's syndrome, a rare but often fatal condition. Caution should be used in administering ASA-containing medications to young adults who have fever, flu or chicken pox. FIORINAL*-C should not be administered to children.

Before you have any medical tests done, tell the person in charge that you are taking FIORINAL*-C. ASA and codeine may interfere with the results of certain tests done in blood and urine.

Driving and operating machinery

FIORINAL*-C may impair the mental and/or physical abilities required for performance of potentially hazardous task such as driving a car or operating machinery. If you experience drowsiness or dizziness, such tasks should be avoided. Avoid alcohol as it can increase drowsiness and dizziness.

Pregnancy, labour and breastfeeding

FIORINAL*-C is not recommended during pregnancy because it may cause withdrawal symptoms in the newborn baby. When taken close to delivery it may make delivery longer or lead to bleeding and other serious complications in the mother or in the newborn baby.

FIORINAL*-C passes into breast milk and may harm a nursing infant. Certain nursing mothers taking FIORINAL*-C can have higher morphine levels in their breast milk. These higher levels of morphine in breast milk may lead to life-threatening side in nursing babies or death. Contact your doctor immediately if you are breastfeeding and your baby is having difficulty breathing or feeding, or is very sleepy or limp.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other prescription or over-the-counter medicines, vitamins or natural health products during your treatment with FIORINAL*-C.

Check with your doctor or pharmacist before taking any other medication with FIORINAL*-C.

Tell your doctor if you are taking any of the following medications:

- alcohol and other CNS depressants (such as sleeping pills, muscle relaxants, pain killers, allergy medication (antihistamines), drugs used to treat anxiety, panic attacks and seizures)
- monoamine oxidase (MAO) inhibitors (e.g., phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- corticosteroids
- oral drugs to treat diabetes and/or insulin
- blood thinners such as warfarin
- drugs used to suppress the immune system such as 6-mercaptopurine and methotrexate
- NSAIDs (non-steroidal anti-inflammatory drugs) to treat pain such as ibuprofen and naproxen
- tranquilizers such as chlordiazepoxide
- drugs used to treat gout such as probenecid and sulfinpyrazone
- birth control pills.

PROPER USE OF THIS MEDICATION

Take FIORINAL*-C exactly as directed by your doctor.

Usual dose (adults 18 years and older):

Take 1 or 2 capsules at once, followed if necessary, by 1 capsule every 4 to 6 hours. Do not take more than 6 capsules daily or as prescribed.

Your doctor should prescribe FIORINAL*-C at the lowest effective dose for the shortest period of time. Take FIORINAL*-C every 4 to 6 hours, as needed.

FIORINAL*-C comes as a capsule to take by mouth.

Overdose:

The most important sign of overdose is decreased breathing (abnormally slow or weak breathing), dizziness, confusion or extreme drowsiness. If you accidentally take too much FIORINAL*-C, call your doctor and/or your local emergency number and/or a Regional Poison Control Centre immediately, or go to a hospital emergency and take any remaining tablets and the container with you, even though you may not feel sick.

Missed Dose:

If you forget to take a dose of FIORINAL*-C, do not worry. Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for the missed one.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, FIORINAL*-C may cause unwanted reactions called side effects. Not all of these side effects may occur. Check with your doctor if the unwanted effects do not go away during treatment or become bothersome.

The following side effects may occur during treatment:

- nausea, vomiting, indigestion and/or stomach pain
- drowsiness, lightheadedness and dizziness
- constipation and gas
- skin rash and itching
- small pupils
- fast or irregular heart beat
- irritability
- tremor
- lack of coordination
- difficulty thinking
- poor memory and judgement
- decreased attention
- mood swings
- exaggeration of personality traits.

If any of these side effects affects you severely, tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Uncommon	Reye's syndrome: rash on the palms of hands and feet, severe vomiting, high fever, weakness, confusions, headache, fast breathing leading to unresponsiveness and death			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek
	Allergic reactions: itching, rash, hives, difficulty breathing or swallowing not present before using this medicine			√
Unknown	Pancreatitis: severe stomach pain with radiation through to the back, nausea and vomiting		√	
	Serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson syndrome erythema multiforme and exfoliative dermatitis: fever, itching, skin sores			√
	Anemia: fatigue, breathing difficulties, irregular heart beat or pale skin	√		
	Stomach ulcer: heartburn, long lasting stomach pain, loss of appetite and weight loss		√	
	Prolonged bleeding time	√		
	Hepatitis: loss of appetite, dark urine, yellowing of eyes and skin		√	
	Blood in the stool		√	

This is not a complete list of side effects. For any unexpected effects while taking FIORINAL-C, contact your doctor or pharmacist.*

HOW TO STORE IT

- store your FIORINAL*-C capsules at room temperature (between 15-30°C)
- keep out of reach and sight of children
- discard any expired medicine or medicine no longer needed.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

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