

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PATIENT MEDICATION INFORMATION**

**<sup>N</sup>FIORINAL<sup>®</sup>-C ¼**

**<sup>N</sup>FIORINAL<sup>®</sup>-C ½**

**(acetylsalicylic acid-caffeine-codeine-butalbital)**

**USP**

Read this carefully before you start taking FIORINAL<sup>®</sup>-C and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about FIORINAL<sup>®</sup>-C.

### Serious Warnings and Precautions

- **Even if you take FIORINAL<sup>®</sup>-C as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **When you take FIORINAL<sup>®</sup>-C it must be swallowed whole. Do not cut, break, crush, chew, or dissolve the capsules. This can be dangerous and can lead to death or seriously harm you.**
- **You may get life-threatening breathing problems while taking FIORINAL<sup>®</sup>-C. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your FIORINAL<sup>®</sup>-C. They could die from taking it. If a person has not been prescribed FIORINAL<sup>®</sup>-C, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took FIORINAL<sup>®</sup>-C while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:**
  - **has changes in their breathing (such as weak, difficult or fast breathing)**
  - **is unusually difficult to comfort**
  - **has tremors (shakiness)**
  - **has increased stools, sneezing, yawning, vomiting, or fever****Seek immediate medical help for your baby.**
- **Taking FIORINAL<sup>®</sup>-C with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.**

### **What is FIORINAL<sup>®</sup>-C used for?**

FIORINAL<sup>®</sup>-C, is used in adults for the relief of tension-type headache.

FIORINAL<sup>®</sup>-C is recommended for adults 18 years and older.

### **How does FIORINAL<sup>®</sup>-C work?**

FIORINAL<sup>®</sup>-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 an opioid that relieves pain by acting on specific nerve cells of the spinal cord and brain. Butalbital is a sedative that causes relaxation. This combination is used to relieve tension-type headaches.

### **What are the ingredients in FIORINAL<sup>®</sup>-C?**

Medicinal ingredients: ASA (acetylsalicylic acid), caffeine, codeine and butalbital.

Non-medicinal ingredients: FD&C Blue #1, FD&C Red #3, gelatin, microcrystalline cellulose, pregelatinized starch, stearic acid, talc and titanium dioxide.

### **FIORINAL<sup>®</sup>-C comes in the following dosage forms:**

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

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

### **Do not use FIORINAL<sup>®</sup>-C if:**

- your doctor did not prescribe it for you
- you are allergic to ASA, caffeine, codeine, butalbital or any of the other ingredients in FIORINAL<sup>®</sup>-C capsules (see **What are the ingredients in FIORINAL<sup>®</sup>-C?**)
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- you have severe asthma, trouble breathing, or other breathing problems
- you have any heart problems
- you have bowel blockage or narrowing of the stomach or intestines
- you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you suffer from alcoholism

- you are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- you are going to have, or recently had, a planned surgery
- you are pregnant or planning to become pregnant or you are in labour
- you are breastfeeding. The use of codeine-containing products while breast-feeding may harm your baby. If you breastfeed and take FIORINAL®-C, seek immediate medical care for your baby if they are overly drowsy, sedated, have difficulty breast-feeding, have breathing difficulties, and are floppy (have decreased muscle tone). This is very serious for the baby and can lead to death. Tell the baby's doctor that you are breastfeeding and took FIORINAL®-C.
- you are under 12 years old
- you are less than 18 years old and are having (or have recently had) your tonsils or adenoids removed because of frequent interruption of breathing during sleep
- have a condition that predisposes to bleeding such as hemophilia, hypoprothrombinemia, 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 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 pneumonia (a lung infection)
- have been told by your doctor that you break down codeine rapidly. This can lead to codeine overdose even at the usual adult dose.
- FIORINAL®-C is not recommended in children less than 18 years old.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FIORINAL®-C. Talk about any health conditions or problems you may have, including if you:**

- have a history of illicit or prescription drug or alcohol abuse
- have severe kidney, liver or lung disease
- have heart disease
- have low blood pressure
- have past or current depression
- suffer from chronic or severe constipation
- 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 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
- suffer from migraines
- are planning to become pregnant
- 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.

**Other warnings you should know about:**

FIORINAL<sup>®</sup>-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 Overdose, 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.**

**Opioid dependence and addiction:** There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

FIORINAL<sup>®</sup>-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<sup>®</sup>-C. Physical dependence may lead to withdrawal side effects when you stop taking this medicine. Continuous daily use of FIORINAL<sup>®</sup>-C should be avoided as medication overuse (rebound) headaches may result in addition to the tolerance and dependence risks. Patients should take FIORINAL<sup>®</sup>-C only for as long as it is prescribed, in the amounts prescribed, and no more frequently than prescribed.

**Reye's syndrome:** 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<sup>®</sup>-C should not be administered to children.

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

**Pregnancy, nursing, labour and delivery:** Do not use FIORINAL<sup>®</sup>-C while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. FIORINAL<sup>®</sup>-C can then cause life-threatening breathing problems in your unborn baby or nursing infant.

**Driving and using machines:** Before you do tasks which may require special attention, you should wait until you know how you react to FIORINAL<sup>®</sup>-C. FIORINAL<sup>®</sup>-C can cause:

- drowsiness
- dizziness or
- lightheadedness

This can usually occur after you take your first dose and when your dose is increased.

**Disorder of the adrenal gland:** You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off FIORINAL<sup>®</sup>-C.

**Serotonin Syndrome:** FIORINAL<sup>®</sup>-C can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take FIORINAL<sup>®</sup>-C with certain anti-depressants or migraine medications.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

**Sexual Function/Reproduction:** Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with FIORINAL<sup>®</sup>-C:**

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking FIORINAL<sup>®</sup>-C. It can lead to:
  - drowsiness
  - unusually slow or weak breathing
  - serious side effects or
  - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by FIORINAL<sup>®</sup>-C
- other opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take FIORINAL<sup>®</sup>-C with MAO inhibitors (MAOi) or if you have taken MAOi's in the last 14 days.
- triptans used to treat migraines (e.g. oxitriptan)
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- some heart medications (such as beta blockers)
- St. John's Wort
- warfarin (such as Coumadin<sup>®</sup>) and other anticoagulants (used for prevention or treatment of blood clots)
- drugs used to treat panic attacks and seizures
- corticosteroids
- oral drugs to treat diabetes and/or insulin
- 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
- drugs used to treat gout such as probenecid and sulfinpyrazone
- birth control pills

**How to take FIORINAL<sup>®</sup>-C:**

**Swallow whole. Do not cut, break, crush, chew or dissolve the capsules. This can be dangerous and can lead to death or seriously harm you.**

### **Usual Adult Starting Dose:**

Your dose is tailored/personalized just for you. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor.

Your doctor will prescribe the lowest effective dose for the shortest period of time that works to control your pain. It is recommended that you only take FIORINAL<sup>®</sup>-C for up to 3 days. If you need to take FIORINAL<sup>®</sup>-C for longer, your doctor will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose.

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

FIORINAL<sup>®</sup>-C comes as a capsule to take by mouth.

Review your pain regularly with your doctor to determine if you still need FIORINAL<sup>®</sup>-C. Be sure to use FIORINAL<sup>®</sup>-C only for the condition for which it was prescribed.

Let your doctor know rapidly if no effective pain relief is achieved after 3 days of treatment.

If your pain increases or you develop any side effect as a result of taking FIORINAL<sup>®</sup>-C, tell your doctor immediately.

### **Stopping your Medication**

If you have been taking FIORINAL<sup>®</sup>-C for more than a few days you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking FIORINAL<sup>®</sup>-C. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness

- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking FIORINAL<sup>®</sup>-C.

### **Refilling your Prescription for FIORINAL<sup>®</sup>-C:**

A new written prescription is required from your doctor each time you need more FIORINAL<sup>®</sup>-C. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your tension headaches.

### **Overdose:**

If you think you have taken too much FIORINAL<sup>®</sup>-C, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

### **Missed Dose:**

If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in a row, talk to your doctor before restarting your medication.

### **What are possible side effects from using FIORINAL<sup>®</sup>-C?**

These are not all the possible side effects you may feel when taking FIORINAL<sup>®</sup>-C. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Lightheadedness
- Insomnia
- Dizziness
- Fainting

- Nausea, vomiting, or a poor appetite
- Indigestion and/or stomach pain
- Dry mouth
- Headache
- Difficulty thinking
- Poor memory and judgement
- Decreased attention
- Problems with vision
- Small pupils
- Fast or irregular heart beat
- Irritability
- Mood swings exaggeration of personality traits
- Weakness, uncoordinated muscle movement
- Tremor
- Skin rash and itching
- Sweating
- Constipation and gas
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using FIORINAL<sup>®</sup>-C.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>  <b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			√
<b>Respiratory Depression:</b> Slow, shallow or weak breathing.			√
<b>Bowel Blockage (impaction):</b> abdominal pain, severe constipation, nausea			√

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		√	
<b>Fast, Slow or Irregular Heartbeat:</b> heart palpitations.		√	
<b>Low Blood Pressure:</b> dizziness, fainting, light-headedness.	√		
<b>Serotonin Syndrome:</b> agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			√
<b>UNCOMMON</b>			
<b>Reye's syndrome:</b> rash on the palms of hands and feet, severe vomiting, high fever, weakness, confusions, headache, fast breathing leading to unresponsiveness and death			√
<b>Allergic Reaction:</b> itching, rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
<b>UNKNOWN</b>			
<b>Pancreatitis:</b> severe stomach pain with radiation through to the back, nausea and vomiting		√	
<b>Serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme and exfoliative dermatitis:</b> fever, itching, skin sores			√
<b>Anemia:</b> fatigue, breathing difficulties, irregular heart beat or pale skin	√		

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Stomach ulcer:</b> heartburn, long lasting stomach pain, loss of appetite and weight loss		√	
Prolonged bleeding time	√		
<b>Hepatitis:</b> loss of appetite, dark urine, yellowing of eyes and skin		√	
Blood in the stool		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.

**3 ways to report:**

- Online at MedEffect: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>).

*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.*

**Storage:**

- **Keep unused or expired FIORINAL<sup>®</sup>-C in a secure place to prevent theft, misuse or accidental exposure.**
- Store your FIORINAL<sup>®</sup>-C capsules at room temperature (between 15-30°C).
- **Keep FIORINAL<sup>®</sup>-C under lock, out of sight and reach of children and pets.**

- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes FIORINAL<sup>®</sup>-C, get emergency help right away.**

**Disposal:**

**FIORINAL<sup>®</sup>-C should never be thrown into household trash, where children and pets may find it.** It should be returned to a pharmacy for proper disposal.

**If you want more information about FIORINAL<sup>®</sup>-C:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer medication information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.aralez.com>, or by calling 1-866-391-4503.

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