

Fiorinal®, generics shortage

Health Canada approved products¹

DIN	BRAND NAME	INGREDIENTS	AMOUNT
00176206	FIORINAL C1/2	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	30 MG
00176192	FIORINAL C1/4 CAP	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	15 MG
00226327	FIORINAL CAP	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
02229736	PRONAL TAB	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
00608211	RATIO-TECNAL TAB	ACETYLSALICYLIC ACID	330 MG
00608238	RATIO-TECNAL CAP	BUTALBITAL	50 MG
		CAFFEINE	40 MG
00608181	RATIO-TECNAL C 1/2	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	30 mg
00608203	RATIO-TECNAL C1/4	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	15 mg
01971417	TRIANAL CAP	ACETYLSALICYLIC ACID	330 MG
01971409	TRIANAL TAB	BUTALBITAL	50 MG
		CAFFEINE	40 MG
02242406	TRIANAL-C 1/4	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	15 mg
01971387	TRIANAL-C 1/2 CAPSULE	ACETYLSALICYLIC ACID	330 MG
		BUTALBITAL	50 MG
		CAFFEINE	40 MG
		CODEINE PHOSPHATE	30 mg

Approved Indications: Relief of tension headaches.² Not a good choice for treatment of frequent headaches because evidence of benefit for recurrent headaches is lacking and repeated use can cause medication overuse headaches and dependence on butalbital (+/- codeine).^{2,3}

Off label: Migraine headaches – although used off-label for this indication, there is no evidence to support the use of butalbital-containing products for migraine headache.⁴

Alternatives: NSAIDs, ASA or acetaminophen with or without codeine for tension and migraine headache; ergot derivatives and triptans for migraine headache.^{3,4}

Considerations when stopping Fiorinal®, generics:

- Butalbital dependence – barbiturate withdrawal symptoms can be life threatening if patient has been taking a high dose on a regular basis.⁵ Ideally the patient would be gradually tapered off the product before stopping.^{5,6}
 - Incidence and severity of withdrawal effects are dependent on prior usage⁴
 - Unlikely: < 6 doses daily or short-term use
 - Mild: 7 – 12 doses daily continuously
 - Severe: > 12 doses/daily continuously
 - Withdrawal effects: Initially restlessness, anxiety, weakness, nausea, vomiting and cramps. Major concerns are seizures and delirium which may occur during the second or third day of abstinence. Symptoms typically resolve after eight or more days.⁴⁻⁶
 - Phenobarbital can be used to replace butalbital to prevent or minimize withdrawal effects if butalbital-containing product is abruptly stopped. **Conversion factor is 30 mg/day phenobarbital for every 100 mg/day butalbital.** Taper phenobarbital at rate of 30 mg every 2 to 3 days or more slowly if withdrawal symptoms develop.⁴⁻⁶
 - Benzodiazepines and /or beta-blockers can be used short-term to relieve withdrawal symptoms.⁵
- Medication overuse headache – treatment can include starting a prophylactic medication and abortive agents such as dihydroergotamine or a **triptan** for treatment of the migraine headaches that emerge.³

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References:

1. Health Canada. Drug Product Database. Available at <http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp> . Accessed February, 2013.
2. e-CPS [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2013 Fiorinal. Available from: www.e-cps.ca by subscription. Accessed Feb. 2013.
3. Purdy RA. Headache in adults. In: Gray Jean, editor. e-Therapeutics+ [Internet]. Ottawa (ON): Canadian Pharmacists Association; c2013. Available from: <http://www.e-therapeutics.ca>. Also available in paper copy from the publisher.
4. McLean W, Boucher A et al. Is there an indication for the use of barbiturate-containing analgesic agents in the treatment of pain? Guidelines for the safe use and withdrawal management. *Can J Clin Pharmacol* 2000;7:191-7.
5. http://www.medscape.com/viewarticle/441288_8
6. Loder E, Biondi D. Oral phenobarbital loading: a safe and effective method of withdrawing patients with headache from butalbital compounds. *Headache* 2003;43:904-909.
7. Treatment of medication overuse headache – guideline of the EFNS headache panel *European Journal of Neurology* 2011, 18: 1115–1121
8. Maizels M. The patient with daily headaches. *Am Fam Physician*. 2004 Dec 15;70:2299-2306.