



Therapeutic Class ReviewSM

Opioid Analgesics -- PalladoneTM

May 2005

New Product for Review:

hydromorphone ER capsule (PalladoneTM)
[Purdue Pharma L.P.]

Dossier Provided by Manufacturer: No

Quality of Dossier: not available

Executive Summary

- Hydromorphone extended-release [24h] capsules (Palladone) offer the convenience of once daily dosing.
- There is no evidence that hydromorphone extended-release [24h] capsules (Palladone) provide any additional clinical benefit over hydromorphone or other immediate-release oral opioid analgesics in the treatment of chronic pain.
- There is no evidence that hydromorphone extended-release [24h] capsules (Palladone) provide any additional clinical benefit over other preferred/formulary extended-release opioid analgesics in the treatment of chronic pain.
- The Food and Drug Administration (FDA) has expressed concern over the safety of Palladone.
- Palladone labeling includes a Black Box Warning to emphasize the potential for accidental overdose, misuse, abuse and diversion.

Decision

Maintain hydromorphone extended-release [24h] capsules (Palladone) as non-formulary/non-preferred because there is no additional clinical benefit for its additional cost.

Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose/Route	Potential Off-Label Uses
fentanyl patch (Duragesic [®]) ^{1,2}	8/1990	Management of chronic pain in patients who require continuous opioid for pain that cannot be managed by lesser means	25-100 mcg topically per day (patches replaced q72 hr)	Meniere's disease
hydromorphone tablet ^{1,3} (generic)	12/1992	Management of moderate to severe pain	2-4 mg orally every 3 to 4 hours (chronic)	cough
hydromorphone ER capsule (Palladone TM) ⁴	9/2004	Management of persistent, moderate to severe pain in	12-32 mg orally once per day	

		patients requiring continuous around the clock analgesia with a high potency opioid for an extended period of time, generally weeks to months or longer.		
levorphanol ⁵ (generic)	1/1953	Management of pain when an opioid analgesic is appropriate	2-4 mg orally every 6 to 8 hours (chronic)	
methadone tablet ^{1,6} (generic)	8/1947	(1) Severe pain (2) Detoxification and treatment of narcotic addiction	2.5 to 10 mg orally every 3 to 4 hours (chronic)	restless leg syndrome
morphine sulfate tablet ^{1,7} (generic)	not available	For relief of moderate to severe pain	15-30 mg orally every 3 to 4 hours (chronic)	secretory diarrhea
morphine SR tablet ^{1,8} (generic)	5/1987	For relief of moderate to severe pain in patients who require repeated dosing of a potent opioid analgesic for a period of more than a few days	30-100 mg orally twice daily	secretory diarrhea
morphine SR capsule ⁹ (Kadian [®])	7/1996	For management of moderate to severe pain when treatment with an opioid analgesic is needed for an extended period of time	20-100 mg orally once to twice a day	secretory diarrhea
oxycodone tablet ¹ (generic)	not available	For relief of moderate to moderately-severe pain	5-30 mg orally every 4 to 6 hours	secretory diarrhea, restless leg syndrome
oxycodone ER tablet ^{1,10} (OxyContin [®]) [80 mg tablet is available as a generic product]	12/1995	Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time	20-80 mg orally twice daily	secretory diarrhea

References

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