Anjeso (meloxicam)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Anjeso
- **Generic name:** Meloxicam
- **Pharmacologic class:** Nonsteroidal anti-inflammatory drug (NSAID)
- **Strength and Formulation:** 30mg/mL; per vial; aqueous dispersion for IV injection; contains sucrose
- **Manufacturer:** Baudax Bio
- **How supplied:** Single-dose vial—1
- **Legal Classification:** Rx

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Anjeso


NDC 71518-001-01
Rx Only
Anjeso™
(meloxicam) injection
30 mg/mL
1 mL Single-dose Vial
Discard unused portion.
For Intravenous Use Only
Keep vial in carton to protect from light.

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Indication

- For use in adults for the management of **moderate to severe pain**, alone or in combination with non-NSAID analgesics

Limitation of Use

- Because of **delayed onset** of analgesia, Anjeso alone is not recommended for use when rapid onset of analgesia is required

Dosage and Administration

- Use for shortest duration; individualize
- Administer by IV bolus injection over 15 seconds
- **30mg once daily**
- Monitor patient response
- Median time to meaningful pain relief was 2-3 hours after administration in 2 clinical studies; a non-NSAID analgesic with rapid onset may be needed in certain situations
- For patients who may not experience adequate analgesia for the entire 24-hour dosing interval, a short-acting, non-NSAID, immediate-release analgesic may be necessary

Considerations for Special Populations

- **Pregnancy:** may cause premature closure of the fetal ductus arteriosus; avoid use starting at 30 weeks gestation
- **Females of reproductive potential**: consider withdrawal in women who have difficulties conceiving or who are undergoing investigation of infertility
- **Males of reproductive potential**: may compromise fertility; not known if these effects are reversible
- **Nursing mothers**: no data on presence in human milk
- **Pediatric**: safety, effectiveness not established
- **Geriatrics**: no overall differences observed, however elderly patients are generally at greater risk for NSAID-associated serious cardiovascular, GI, and/or renal adverse reactions

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Considerations for Special Populations

- **Hepatic impairment**: monitor patients with severe impairment
- **Renal impairment**: not recommended in patients with moderate to severe insufficiency; contraindicated in those with moderate to severe insufficiency who are at risk for renal failure due to volume depletion
- **Poor metabolizers of CYP2C9 substrates**: consider dose reduction as these patients may have abnormally high plasma levels due to reduced metabolic clearance, and monitor for adverse effects

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Boxed Warnings

- Risk of serious **cardiovascular adverse events**
  - Increased risk of serious CV thrombotic events, including myocardial infarction and stroke, which can be fatal
  - Risk may occur early in treatment and may increase with duration of use
  - Anjeso contraindicated in the setting of coronary artery bypass graft surgery
- Risk of serious **gastrointestinal adverse events**
  - Increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal
  - Events can occur at any time during use and without warning symptoms
  - Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events

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Contraindications

- Known hypersensitivity to meloxicam or any components of the drug product
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
- In the setting of coronary artery bypass graft surgery
- Moderate to severe renal insufficiency patients who are at risk for renal failure due to volume depletion

Warnings/Precautions

- Increased risk of serious cardiovascular events
- Avoid in recent MI, severe HF, advanced renal disease; if necessary, monitor
- Increased risk of serious GI adverse events (including inflammation, bleeding, ulceration, perforation)
- History of ulcer disease and/or GI bleeding
- Advanced liver disease and/or coagulopathy
- Discontinue if signs/symptoms of liver disease develop, or if systemic manifestations (eg, eosinophilia, rash) occur

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Warnings/Precautions

- Hypertension; monitor BP closely
- Dehydration
- Hypovolemia
- Hyperkalemia
- Pre-existing asthma
- Discontinue at 1st sign of rash or any other hypersensitivity
- Coagulation disorders
- Monitor CBCs, blood chemistry, hepatic, and renal function in long-term therapy
- May mask signs of infection or fever

Interactions

- Avoid concomitant aspirin (at analgesic doses), other NSAIDs, or salicylates (eg, diflunisal, salsalate)
- Increased risk of GI bleed with anticoagulants (eg, warfarin), antiplatelets, oral corticosteroids, SSRIs, SNRIs, smoking, alcohol, or prolonged NSAID therapy; monitor
- May antagonize or increase risk of acute renal failure (esp. in elderly, volume-depleted, or have renal impairment) with ACE inhibitors, ARBs, β-blockers, diuretics; monitor

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Interactions

- May potentiate lithium, methotrexate, cyclosporine; monitor for toxicity
- Concomitant pemetrexed may increase risk of pemetrexed-associated myelosuppression, renal, and GI toxicity
- May be potentiated by CYP2C9 inhibitors (eg, amiodarone, fluconazole, sulphaphenazole); monitor and consider dose reduction

Adverse Reactions

- **Most frequent** (incidence ≥2% and greater than placebo): constipation, increased GGT, anemia
- **Others**: elevated ALT/AST, cardiovascular events, GI bleed/ulcer, edema, hyperkalemia, anaphylactic reactions, rash, hepatotoxicity, renal papillary necrosis, acute renal failure

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Mechanism of Action

- Meloxicam, an **NSAID**, has analgesic, anti-inflammatory, and antipyretic properties
- Because meloxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues

Pharmacokinetics

- ~99.4% protein bound
- Extensively metabolized in the liver (primarily CYP2C9)
- Mean elimination half-life ~24 hours
- Excreted in urine and feces

Clinical Trials

- Safety and efficacy evaluated in two phase 3 double-blind, placebo-controlled, multiple-dose trials in patients with postoperative pain
- In both trials, oral oxycodone 5mg was permitted as rescue medication

Clinical Trials

Study 1: Bunionectomy Surgery

- 201 patients treated with Anjeso 30mg or placebo administered once daily for 2 days starting day after surgery (optional third dose permitted prior to discharge)
- Minimum postop baseline pain intensity of 4 on Numeric Pain Rating Scale (NPRS) (range 1-10) and pain categorized as moderate or severe were required for randomization
- Mean overall baseline pain intensity on NPRS: 6.8
- Average age: 48 years; 85% female

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Clinical Trials

Results

- Statistically significant difference demonstrating efficacy observed in the primary efficacy end point of the summed pain intensity difference over the first 48 hours ($SPID_{48}$)
- Generally consistent separation in pain scores between the Anjeso and placebo groups observed from time of onset through most of the dosing interval with a narrowing at the end of the first 24-hour dosing interval

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Clinical Trials

Study 2: Abdominoplasty Surgery

- 219 patients treated with Anjeso 30mg or placebo administered once daily for 2 days starting on day of surgery (optional third dose permitted prior to discharge)
- Minimum postop baseline pain intensity of 4 on NPRS and pain categorized as moderate or severe were required for randomization
- Mean overall baseline pain intensity on NPRS: 7.3
- Average age: 40 years; 98% female

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Clinical Trials

Results

- Statistically significant difference demonstrating efficacy observed in the primary efficacy end point of the summed pain intensity difference over the first 24 hours ($SPID_{24}$) as well as over the first 48 hours ($SPID_{48}$)
- Generally consistent separation in pain scores between the Anjeso and placebo group observed from time of onset through most of the dosing interval with a narrowing at the end of the first 24-hour dosing interval

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Clinical Trials

- **Median time to first rescue analgesic use** in patients treated with Anjeso (2 hours in Study 1 and 1 hour in Study 2) came before the median time to patient-reported meaningful pain relief in both studies (2 hours in Study 1 and 3 hours in Study 2)
- **Study 1:** 50% of Anjeso-treated patients and 49% of placebo-treated patients received rescue analgesia in the first 2 hours after the start of dosing
- **Study 2:** 78% of Anjeso-treated patients and 78% of placebo-treated patients received rescue analgesia in the first 3 hours after the start of dosing

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/anjeso/