

Consensi[®] (amlodipine/celecoxib) – New drug approval

- On May 31, 2018, [Kitov Pharma announced](#) the [FDA approval](#) of [Consensi \(amlodipine/celecoxib\)](#), for patients for whom treatment with [amlodipine](#) for hypertension and [celecoxib](#) for osteoarthritis are appropriate.
 - Amlodipine is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events (CV), primarily strokes and myocardial infarctions (MI). Amlodipine may be used alone or in combination with other antihypertensive agents.
 - Celecoxib is indicated for the management of the signs and symptoms of osteoarthritis.
 - Consensi is inappropriate for short-term or intermittent treatment or to treat any conditions other than hypertension in patients taking celecoxib for osteoarthritis.
 - Consensi is only available in a celecoxib strength of 200 mg and is only to be taken once daily.
- There are no studies of the combination of celecoxib and amlodipine demonstrating reductions in the signs and symptoms of osteoarthritis, but one of the components, celecoxib, has demonstrated such effects. There are also no long-term studies to evaluate CV safety for the combination of celecoxib and amlodipine.
- The combination of celecoxib and amlodipine was studied in a placebo-and active-controlled study in 152 patients with newly diagnosed hypertension. The patients were randomized to 200 mg celecoxib plus 10 mg amlodipine, 10 mg amlodipine, 200 mg celecoxib, or placebo.
 - The trial results demonstrated that the combination of celecoxib and amlodipine provided similar blood pressure reduction to an equal dose of amlodipine.
 - For additional efficacy and safety information, refer to the individual drug labels for amlodipine and celecoxib.
- Consensi carries a boxed warning for risk of serious CV and gastrointestinal events.
- Consensi is contraindicated in the following patients: known hypersensitivity to amlodipine, celecoxib, or any inactive ingredients of Consensi; history of asthma, urticaria, or other allergic-type reactions after taking [aspirin](#) or other nonsteroidal anti-inflammatory drugs; in the setting of coronary artery bypass graft surgery, and demonstrated allergic-type reactions to sulfonamides.
- Other warnings and precautions of Consensi include hepatotoxicity and patients with hepatic failure; hypertension; hypotension; increased angina or MI; heart failure and edema; renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; premature closure of fetal ductus arteriosus; hematological toxicity; masking of inflammation and fever; and laboratory monitoring.
- The most common adverse reactions (> 2% and > placebo) with celecoxib use in arthritis trials were abdominal pain, diarrhea, dyspepsia, flatulence, peripheral edema, accidental injury, dizziness, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, and rash.
- The most common adverse reaction with amlodipine use in a dose related manner is edema. Other adverse reactions (not dose related, but > 1%) were fatigue, nausea, abdominal pain, and somnolence.

- The recommended starting dosage of Consensi is 5 mg/200 mg orally once daily or 2.5 mg/200 mg in small, fragile, or elderly patients, or patients with mild hepatic insufficiency.
 - Use 2.5 mg/200 mg when adding Consensi to other antihypertensive therapy.
 - Use the lowest effective dosage of celecoxib for the shortest duration consistent with individual patient treatment goals.
 - The maximum dose is 10 mg/200 mg once daily.
- Kitov Pharma’s launch plans for Consensi are pending. Consensi will be available as 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg tablets.



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