

# Important Safety Information (ISI) for Consensi®

## WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

*See full prescribing information for complete boxed warning.*

**CONSENSI contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:**

- Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase with duration of use.
- Do not take CONSENSI right before or after a heart surgery called a “coronary artery bypass graft” (CABG).
- Avoid taking CONSENSI after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.
- NSAID medications, like celecoxib, cause an increased risk of bleeding, ulcers, and tears (perforation) of the esophagus, stomach, and intestines, at any time during treatment, which can occur without warning and may cause death. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

### What is the most important information I should know about CONSENSI?

**Consensi contains celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), and amlodipine, a calcium channel blocker (CCB). NSAIDs can cause serious side effects, including:**

- Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

**Do not take Consensi right before or after a heart surgery called a “coronary artery bypass graft” (CABG).**

**Avoid taking Consensi after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.**

- Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach, and intestines:

- anytime during use
- without warning symptoms
- that may cause death

### The risk of getting an ulcer or bleeding increases with:

- past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- taking medicines called “corticosteroids”, “antiplatelet drugs”, “anticoagulants”, “selective serotonin reuptake inhibitors (SSRIs)”, or “serotonin norepinephrine reuptake inhibitors (SNRIs)”
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

**You should not take other medicines that contain NSAIDs or salicylates during treatment with Consensi because of increased risk of stomach problems. Taking other medicines that contain NSAIDs or salicylates during treatment with Consensi will not provide increased relief of symptoms of osteoarthritis.**

### Consensi should only be used:

- exactly as prescribed
- at the lowest dose possible for your treatment
- for the shortest time needed

### Who should not take CONSENSI?

Do not take Consensi:

- if you are allergic to amlodipine, celecoxib or any of the inactive ingredients in Consensi.
- if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- right before or after heart bypass surgery.
- if you have had an allergic reaction to sulfonamides.

**Before taking Consensi, tell your healthcare provider about all your medical conditions, including if you:**

- have heart problems.
- have liver or kidney problems.
- have asthma.
- are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking Consensi during pregnancy. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take NSAIDs after about 30 weeks of pregnancy.**

- are breastfeeding or plan to breastfeed. Consensi can pass into your breast milk. It is not known if Consensi will harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take Consensi.

**Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Consensi and some other medicines can interact with each other and cause serious side effects. Do not start taking any new medicine without talking to your healthcare provider first.**

### What are the possible side effects of Consensi?

**Consensi can cause serious side effects, including:**

- liver problems, including liver failure
- worsening chest pain (angina) or heart attack, particularly in people with severe obstructive coronary artery disease
- heart failure
- swelling of your arms, legs, hands and feet (peripheral edema) is common with CONSENSI but can sometimes be serious.
- kidney problems, including kidney failure
- increased potassium levels (hyperkalemia)
- life-threatening allergic reactions
- life-threatening skin reactions
- low red blood cells (anemia)

See “What is the most important information I should know about Consensi?” for further detail regarding serious side effects.

Your healthcare provider will monitor your blood pressure and do blood tests to check you for side effects during treatment with Consensi.

Consensi may cause fertility problems in females that is reversible when treatment with Consensi is stopped. Talk to your healthcare provider if this is a concern for you.

### The most common side effects of Consensi include:

- swelling of the arms, legs, hands, and feet
- joint swelling
- dizziness
- stomach pain
- diarrhea
- heartburn
- headache
- frequent urination
- hot or warm feeling in your face (flushing)
- gas
- tiredness
- extreme sleepiness

### Get emergency help right away if you get any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

### Stop taking Consensi and call your healthcare provider right away if you get any of the following symptoms:

- nausea
- more tired or weaker than usual
- diarrhea
- itching
- indigestion or stomach pain
- flu-like symptoms
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- your skin or eyes look yellow
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet

These are not all the possible side effects of Consensi.

**Please see** Full Prescribing Information, including BOXED WARNING, and Medication Guide.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You may also report side effects to Burke Therapeutics, LLC at 1-888-275-1264.