

Medication Guide

SEGLENTIS ["Seg-LEN-tis"]

(celecoxib and tramadol hydrochloride) tablets, CIV

SEGLENTIS is:

- A strong prescription pain medicine that contains the opioid (narcotic) tramadol and the Nonsteroidal Anti-inflammatory Drug (NSAID) celecoxib.
- SEGLENTIS is used for the management of acute pain in adults, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about SEGLENTIS:

- **Get emergency help or call 911 right away if you take too much SEGLENTIS (overdose).** When you first start taking SEGLENTIS, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking SEGLENTIS with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your SEGLENTIS. They could die from taking it. Selling or giving away SEGLENTIS is against the law.
- Store SEGLENTIS securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.
- Celecoxib 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 NSAIDs right before or after a heart surgery called a "coronary artery bypass graft" (CABG).

Avoid taking NSAIDs 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", "SSRIs" or "SNRIs"
- increasing doses of NSAIDs
- longer use of NSAIDs
- smoking
- drinking alcohol
- older age
- poor health
- advanced liver disease
- bleeding problems

Important Information Guiding Use in Pediatric Patients:

- Do not give SEGLENTIS to a child younger than 12 years of age.
- Do not give SEGLENTIS to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving SEGLENTIS to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.

Do not take SEGLENTIS if you have:

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or narrowing of the stomach or intestines.
- An allergy to tramadol, opioids, celecoxib, sulfonamides, or any of the inactive ingredients in SEGLENTIS.
- Had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.
- Taken a Monoamine Oxidase Inhibitor, MAOI (medicine used for depression) within the last 14 days or are currently taking one.

Do not take SEGLENTIS right before or after heart bypass surgery.

Before taking SEGLENTIS, tell your healthcare provider about all of your medical conditions, including if you have a history of:

- Head injury, seizures
- Liver, kidney, thyroid problems
- Problems urinating
- Pancreas or gallbladder problems
- Abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems
- High blood pressure
- Asthma

Tell your healthcare provider if you:

- **Are pregnant or plan to become pregnant:** Use of SEGLENTIS for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. Taking SEGLENTIS at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take SEGLENTIS 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 SEGLENTIS and other NSAIDs after about 30 weeks of pregnancy.** Tell your healthcare provider if you become pregnant or think that you may be pregnant.
- **Are breastfeeding:** Not recommended; may harm your baby.
- Notice your pain getting worse. If your pain gets worse after you take SEGLENTIS, do not take more of SEGLENTIS without first talking to your doctor. Talk to your doctor if the pain you have increases, if you feel more sensitive to pain, or if you have new pain after taking SEGLENTIS.
- Are living in a household where there are small children or someone who has abused street or prescription drugs.
- Are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. **Taking SEGLENTIS with certain other medicines can cause serious side effects that could lead to death. Do not start taking any new medicine without talking to your healthcare provider first.**

When taking SEGLENTIS:

- Do not change your dose. Take SEGLENTIS exactly as prescribed by your healthcare provider. Use SEGLENTIS at the lowest dosage possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take SEGLENTIS for a few days. You may have some SEGLENTIS left over that you did not use. See disposal information at the bottom of this section for directions on how to safely dispose of SEGLENTIS.
- The maximum dosage is 2 tablets every 12 hours. Do not take more than your prescribed dose and do not take more than 4 tablets per day. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking SEGLENTIS regularly, do not stop taking SEGLENTIS without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused SEGLENTIS immediately by taking your drug to an authorized Drug Enforcement Administration (DEA)-registered collector or drug take-back program. If one is not available, you can dispose of SEGLENTIS by mixing the product with dirt, cat litter, or used coffee grounds, placing the mixture in a sealed plastic bag, and throwing the bag in your trash.

While taking SEGLENTIS DO NOT:

- Drive or operate heavy machinery, until you know how SEGLENTIS affects you. SEGLENTIS can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with SEGLENTIS may cause you to overdose and die.

The possible side effects of SEGLENTIS:

- Constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.
- NSAIDs can cause serious side effects, including: new or worse high blood pressure, heart failure, liver problems including liver failure, kidney problems including kidney failure, low red blood cells (anemia), life-threatening skin reactions, life-threatening allergic reactions. Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

Get emergency medical help or call 911 right away if you have:

- Trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

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

- Nausea, more tired or weaker than usual, diarrhea, itching, your skin or eyes look yellow, 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, skin rash or blisters with fever, swelling of the arms, legs, hands and feet.

SEGLENTIS may cause fertility problems in males and females, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of SEGLENTIS. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

Other information about NSAIDs:

- Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some NSAIDs are sold in lower doses without a prescription (over the counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

General information about the safe and effective use of SEGLENTIS.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SEGLENTIS for a condition for which it was not prescribed. Do not give SEGLENTIS to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about SEGLENTIS, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about SEGLENTIS that is written for health professionals.

Distributed by: Kowa Pharmaceuticals America, Inc. Montgomery, AL 36117 USA. For more information, go to www.seglenisrx.com or call 1-888-SEGLENTIS.

MG-SEG-US-00002 11/2023

SEGLENTIS® is a registered trademark of Esteve Pharmaceuticals, S.A. and is used under license.

© Kowa Pharmaceuticals America, Inc. (2021)

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 12/2023