

Medication Guide
COMBOGESIC (*kom-boh-JEE-zik*)
(acetaminophen and ibuprofen)
tablets

COMBOGESIC is a combination prescription medicine that contains acetaminophen **and** ibuprofen (a nonsteroidal anti-inflammatory drug [NSAID]).

What is the most important information I should know about COMBOGESIC?

COMBOGESIC may cause serious side effects, including:

- **Severe liver problems.** Acetaminophen, one of the ingredients in COMBOGESIC, has caused severe and life-threatening acute liver failure which caused the need for a liver transplant and has caused death.
 - Taking COMBOGESIC with other products that contain acetaminophen can lead to serious severe liver problems and death. **Do not take COMBOGESIC with other acetaminophen containing products.**
 - **You should not take more than 3 COMBOGESIC tablets in one dose or more than 12 COMBOGESIC tablets in one day.**
 - If you take too much COMBOGESIC or acetaminophen, call your healthcare provider or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.
- **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 medicines containing NSAIDs
 - with longer use of medicines containing NSAIDs

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

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

COMBOGESIC should only be taken exactly as prescribed, at the lowest dose possible for your treatment, and for the shortest time needed.

What is COMBOGESIC?

COMBOGESIC is a combination prescription medicine that contains acetaminophen and ibuprofen (a non-steroidal anti-inflammatory drug [NSAID]) used in adults for the short-term management of mild to moderate acute pain. It is not known if COMBOGESIC is safe and effective for use in children.

Do not take COMBOGESIC:

- If you are allergic to acetaminophen, ibuprofen, other NSAIDs, or to any of the ingredients in COMBOGESIC. See the end of this Medication Guide for a complete list of ingredients in COMBOGESIC.
- If you have had an asthma attack, hives, or other allergic reactions after taking aspirin or any other NSAIDs.
- Right before or after heart bypass surgery.

Before taking COMBOGESIC, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have high blood pressure
- have asthma
- have heart problems
- have bleeding problems
- have or have had ulcers
- drink alcohol
- are pregnant or plan to become pregnant. Taking COMBOGESIC 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.**
 - NSAID containing products, including COMBOGESIC, may cause reversible fertility problems in females, which may temporarily affect your ability to become pregnant during treatment with COMBOGESIC. Talk to your healthcare provider if this is a concern for you.
- are breastfeeding or plan to breastfeed. Ibuprofen can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with COMBOGESIC.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

COMBOGESIC 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.**

How should I take COMBOGESIC?

- Take COMBOGESIC exactly as your healthcare provider tells you to take it.
- **You should not take more than 3 COMBOGESIC tablets in one dose or more than 12 COMBOGESIC tablets each day.**
- If you take too much COMBOGESIC, call your healthcare provider or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking COMBOGESIC?

- You should avoid drinking alcohol during treatment with COMBOGESIC. Drinking alcohol during treatment with COMBOGESIC may increase your chances of having serious side effects.

What are the possible side effects of COMBOGESIC?

COMBOGESIC may cause serious side effects, including:

See “What is the most important information I should know about COMBOGESIC?”

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure
- high potassium level in your blood (hyperkalemia)

- life-threatening allergic reactions
- life-threatening skin reactions
- low red blood cells (anemia)
- changes in your vision

Other side effects of COMBOGESIC include: nausea, vomiting, headache, dizziness, sleepiness, bleeding after medical procedures, swelling of the face.

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

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

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

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

These are not all the possible side effects of COMBOGESIC.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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 COMBOGESIC.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COMBOGESIC for a condition for which it was not prescribed. Do not give COMBOGESIC to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about COMBOGESIC that is written for health professionals.

What are the ingredients in COMBOGESIC?

Active ingredients: acetaminophen and ibuprofen

Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, medium chain triglycerides, microcrystalline cellulose, polydextrose, povidone-30, sodium lauryl sulfate, talc, titanium dioxide.

Manufactured by: Catalent Greenville Inc, 1240 Sugg Parkway, Greenville, NC 27834. Ph: +1-252-752-3800

Distributed by: AFT Pharmaceuticals US, Inc. 42714 Woodward Ave, Suite B, Bloomfield Hills, MI 48304. Ph: 01-248-631-4810

For more information go to www.aftpharm.com or call: 01-248-631-4810

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

Issued: 11/2024