

COMBESIC 37.5mg/325mg Orally Disintegrating Tablet

Paracetamol 325mg and Tramadol Hydrochloride 37.5mg Tablets

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What Combestic is used for

Combestic is used to treat moderate pain to severe pain.

How Combestic works

Combestic have a combination of two pain relievers – tramadol hydrochloride (an opioid analgesic) and acetaminophen (same as paracetamol).

Before you use Combestic

-When you must not use it

- You are less than 12 years old;
- You have slow or shallow breathing, or other breathing problems;
- You are pregnant;
- You are breastfeeding.

You must not take Combestic if you have previously had an allergic reaction (hypersensitivity) to tramadol hydrochloride or acetaminophen, or to any other opioid pain relievers. Please tell your doctor if this applies to you. Hypersensitivity can be recognized for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

Do not give Combestic to a child under 18 years of age that has just an operation to remove their tonsils or adenoids.

Do not take Combestic if you are taking:

- Sleeping pills e.g. hypnotics;
- Medicines that affect your mood or emotions e.g. narcotics and psychotropic drugs;
- Pain relievers that affect your central nervous system e.g. centrally acting analgesics and opioids;
- Antidepressants such as Monoamine Oxidase Inhibitors (MAO inhibitors) currently or within the last 14 days.

Pregnancy and lactation

If you are, or think you may be, pregnant, you should inform your doctor, who will decide if you can take Combestic.

Opioid medicines can slow the breathing of a newborn child. Prolonged use of Combestic during pregnancy can cause withdrawal symptoms in your new-born baby that could be life-threatening if not recognized and treated. This risk is increased in the last trimester of pregnancy.

Breastfeeding

You are advised not to take Combestic if you are breastfeeding, because Combestic may end up in your milk.

-Before you start use it

Talk to your doctor or pharmacist before taking this medication if you

- suffer from serious liver or kidney disease,
- have diabetes,
- are over 65 years of age,
- have abdominal problems,
- have had a previous head injury,
- have chronic alcoholism,
- are pregnant or plan to become pregnant, are breast-feeding,
- if you are taking any other medications including natural health products, prescription drugs, salicylates, other pain and fever relief medications or nonsteroidal anti-inflammatory drugs (NSAIDs).

This will help your doctor to decide whether you should use Combestic and what extra care should be taken during its use.

-Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines as Combestic may affect how well they work:

- Monoamine Oxidase Inhibitors (MAOIs), used to treat mental conditions such as depression e.g. phenelzine, tranylcypromine. You should not take Combestic with MAOIs or within 14 days of having last taken them;

- Selective Serotonin Reuptake Inhibitors (SSRI's), used to treat depression or Parkinson's Disease;
- Drugs used to treat depression e.g. mirtazapine; tricyclic antidepressants; trazadone;
- Triptans, used to treat migraines;
- 5-HT₃ receptor antagonists, used to treat nausea and vomiting;
- Medicines that slow down your central nervous system such as sedatives, sleeping pills, drugs used for surgery (anesthetics), tranquilizers (benzodiazepines), drugs used to treat certain mental conditions (psychotropic drugs), some strong painkillers (opioids), or alcohol;
- Antibiotics to treat infections, e.g. erythromycin, rifampin, linezolid, flucloxacillin;
- Anti-fungals used to treat fungal infections, e.g. ketoconazole;
- Anti-retrovirals used to treat HIV/AIDs, e.g. ritonavir;
- Phenytoin, used to treat seizures;
- Carbamazepine, used to treat epilepsy and some types of pain;
- Quinidine, used to treat heart conditions (antiarrhythmics);
- Warfarin like compounds, used to stop blood clotting (blood thinners);
- Drugs that slow down or reduce the conversion (metabolism) of this drug to its active form (CYP2D6 inhibitors); e.g. fluoxetine, paroxetine, amitriptyline, and bupropion;
- Cimetidine, used to treat heart burn and peptic ulcers.

Taking Combestic with a benzodiazepine (medicine used as sedatives or treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficulty in breathing, or unresponsiveness.

How to use Combestic

-How to use it

Combestic comes in the form of tablet to be taken by mouth. You can take Combestic at any time of the day with or without food. Do not take more than the

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recommended dose of Combestic. The lowest effective dose should be used for the shortest period of time.

-How much to use

Adults (including elderly) and Children over 16 years: Take 1 to 2 tablets every 4 to 6 hours as needed for pain relief. Do not take more than 8 tablets in a 24-hour period.

Do not take COMBESIC if you have severe liver problems.

Tell your doctor if you have a kidney disorder (a creatinine clearance of less than 30 mL/min). Do not take more than 2 tablets every 12 hours.

If in doubt, ask your doctor or pharmacist for advice.

-When to use it

Always take Combestic exactly as your doctor has told you. You should check with your doctor if you are not sure.

-How long to use it

Continue taking Combestic for as long as your doctor recommends.

-If you forget to use it

If you forget to take the tablet, pain is likely to return.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Tell your doctor immediately if you have taken too much Combestic, especially if you have any of the following symptoms:

Breathing difficulties with slow or shallow breathing and/or fits (seizures), irritation and discomfort in the stomach and gut, loss of appetite, nausea, vomiting, feeling unwell, unusually pale colour and sweating. Cases of abnormal electrical conduction in the heart have been reported.

Your doctor will take the necessary measures.

Accidental swallowing of Combestic tablets, especially by children, can result in breathing difficulties, with slow or shallow breathing, and/or fits (seizures). Deaths have been reported.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Combestic.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not take more than your recommended dose.

Discontinuation:

Stopping the COMBESIC tablets too quickly may cause some side effects, so your doctor may ask you to gradually stop taking your medication over several days. To get the full benefit from your treatment, it is important to take COMBESIC tablets as prescribed.

-Things to be careful of

Tramadol is not to be used during breastfeeding. Small amounts of tramadol are excreted into breast milk. On a single dose, it is usually not necessary to interrupt breastfeeding. If you have taken Combestic when you are breastfeeding, seek immediate medical attention if you notice your baby has any changes in their breathing (such as weak, difficult or fast breathing).

Serotonin syndrome:

Combestic may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency:

Long-term use of Combestic may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs

such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility:

Long-term use of Combestic may cause reduced fertility. It is known whether these effects on fertility are reversible.

Opioids can be abused and misused, and you are at risk for opioids addiction, even if you take your dose as prescribed.

Tell your doctor if you:

- Have an allergic reaction (characterized by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking codeine or other opioids.
- Taking other medicines, which contain tramadol or acetaminophen.
- Taking any medicines, because taking some medicines together with Combestic may increase your risk of fits (seizures).
- Have asthma, any history of serious breathing problems or if you experience breathing difficulties, with slow or shallow breathing.
- Combestic can cause low levels of oxygen in the blood and a problem called sleep apnea (stopping breathing from time to time whilst sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices you stop breathing from time to time whilst sleeping.
- Combestic is not for use in children under 12 years old as it may result in breathing difficulties, with slow or shallow breathing, that could lead to death.
- Taking any drugs that slow down your central nervous system (for example, drugs that make you sleepy, reduce anxiety or decrease awareness). Taking these kinds of drugs with Combestic can cause severe drowsiness, decreased awareness and breathing difficulties, with slow or shallow breathing.
- Have recently suffered from a head injury or severe headaches associated with vomiting.
- Have a history of substance dependence or abuse of drugs, alcohol or any opioid painkillers.

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- Have a history of mental health problems.
- Want to stop taking Combescic. You may become dependent on Combescic and may need to reduce the dose of Combescic slowly to avoid withdrawal symptoms.
- Stop taking Combescic and tell your doctor immediately if you experience skin rash, especially:
 - A red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).
 - A life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis).
 - A severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- Some patients taking this medicine may experience low levels of sodium in the blood (hyponatremia). Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of these symptoms while taking Combescic, tell your doctor immediately.

Warning

This preparation contains
PARACETAMOL.

Do not take any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Alcohol

You should not take Combescic tablets with any alcohol-containing beverages. Also, you should tell your doctor if you drink alcohol regularly, or have a history of alcoholism.

Driving and using machines

Combescic may make you feel tired, dizzy or drowsy. If this happens, do not drive or use any machines.

Side effects

Like all medicines, Combescic can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following side effects while using Combescic:

Common

- Nausea, dizziness, feeling sleepy

Uncommon

- Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Combescic

Storage

Store at below 30°C

Keep out of the reach and sight of children.

Do not store any medicine in the bathroom, or near a sink, or on a window sill. Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Round, white to off white, flat, bevelled edged, tablets with central concave depression on both the surfaces, having mint odour.

Ingredients

Active ingredient

Each tablet of Combescic contains 325 mg of Paracetamol and 37.5 mg of Tramadol Hydrochloride

Inactive ingredients

Silica Colloidal Anhydrous, Povidone K30, Isopropyl Alcohol, Ethylcellulose N7, Mannitol (Pearlitol 25C), Mannitol (Pearlitol 400DC), Mannitol (Pearlitol 50C), Crospovidone, Aspartame, Flavour Peppermint, Magnesium Stearate.

Nature and Contents of Container

Aluminium/PVC blister strips of 10 tablets per strip in unit cartons containing pack sizes of 30's in unit

MAL number:

Combescic 37.5mg/325mg:
MAL*****

Manufacturer

ATHENA DRUG DELIVERY SOLUTIONS PVT. LTD.
PLOT NO. A-1 TO A-5, MIDC, CHEMICAL ZONE, AMBERNATH (W), THANE 421501, MAHARASHTRA STATE, AMBARNATH, INDIA

Product Registration Holder

Mansa Healthcare Sdn Bhd
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1 Mar 2024

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