

ACIDPASS 10/800/165 mg Chewable Tablet

For oral use. · Registration No: XXX · ATC: XXX

Sold Without Prescription

Antacid + H2 Receptor
Blocker

16 Years and
Older

ACTIVE INGREDIENTS

Each chewable tablet contains 10 mg famotidine, 800 mg calcium carbonate and 165 mg magnesium hydroxide.

EXCIPIENTS

Microcrystalline cellulose PH 101, lactose monohydrate (derived from cow's milk), FD&C Red No:40, aluminum lake, magnesium stearate, sucralose, polyacrylate dispersion (30%), hydroxypropylmethyl cellulose, dextrose monohydrate, strawberry flavor.

PACKAGING

Blister pack containing 2, 6 or 12 tablets.

Before you start using this medicine, please read this PACKAGE LEAFLET carefully, as it contains important information for you.

This medicine is for you to obtain without a prescription and to treat a mild illness with the advice of your pharmacist without a doctor's help. However, you still need to use ACIDPASS carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not pass it on to others.
- During the use of this medicine, when you go to the doctor or hospital, tell your doctor that you are using this medicine.
- Follow the instructions in this leaflet exactly. Do not use **high or low doses** other than the dose recommended for you regarding the medicine.

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What is ACIDPASS and what is it used for?

ACIDPASS chewable tablets are pink, round, flat, and unscored chewable tablets. ACIDPASS is available in blister packs of 2, 6 or 12 tablets.

ACIDPASS is used in patients aged 16 years and older to provide fast and long-lasting (up to 12 hours) relief from symptoms caused by heartburn, indigestion, and excess acid. Each chewable tablet contains famotidine, which belongs to a group of medicines known as H2 receptor blockers that help balance the amount of acid produced, along with the active

ingredients calcium carbonate and magnesium hydroxide, which neutralize stomach acid and are known as antacids.

Things to consider before using ACiDPASS

DO NOT USE ACiDPASS in the following situations

If you have,

Hypersensitivity to famotidine, calcium carbonate, or magnesium hydroxide, active ingredients in ACiDPASS chewable tablets, or to any of the excipients used in this medicine,

Hypersensitivity to H₂ receptor antagonists such as cimetidine and ranitidine,

Severe renal failure,

If any of the above situations apply to you, consult your doctor or pharmacist before using ACiDPASS.

USE ACiDPASS CAREFULLY in the following situations

If you have;

Indigestion and also experiencing involuntary weight loss,

Persistent abdominal pain,

Development of indigestion or worsening of indigestion,

High calcium levels in your blood,

High magnesium levels in your blood,

Very low levels of phosphorus in your blood,

High amounts of calcium in your urine or a history of kidney stones,

Kidney or liver problems,

Been told by your doctor that you have an intolerance to certain sugars,

If you use ACiDPASS for a long time, your blood calcium levels may increase. This is more likely if you are also taking other medicines containing calcium and/or vitamin D; your kidneys may be affected.

Stop using this medicine and consult a doctor if the following symptoms occur:

New symptoms

Difficulty swallowing

Pain while swallowing

Severe vomiting

Black stools

Throat blockage or chest pain

If your symptoms persist or worsen after 2 weeks of treatment, consult your doctor before continuing treatment.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using ACiDPASS with food and drink

ACiDPASS has no known interaction with food and drinks.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

If you are pregnant, think you may be pregnant, or are planning to become pregnant, do not use this medicine.

If you realize you are pregnant during your treatment, contact your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before using the medicine.

If you are breastfeeding, consult your doctor before using this medicine. Your doctor will decide whether to stop breastfeeding or ACiDPASS treatment.

Driving and using machines

ACiDPASS is not expected to affect your ability to drive or use machines. However, if dizziness occurs, you should not drive or use machines.

Important information about some excipients contained in ACiDPASS

ACiDPASS chewable tablet contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before using this medicinal product.

Using with other medicines

Since ACiDPASS contains calcium carbonate and magnesium as active ingredients, it should be taken at least 2 hours apart from the following medicines.

Antibiotics (used for bacterial infections)

Beta-blocker drugs (used in the treatment of high blood pressure)

Bisphosphonates (medicines used in the treatment of bone loss)

Glucocorticosteroids (medicines used in the presence of inflammation)

Integrase inhibitors (medicines used in the treatment of HIV (Human Immunodeficiency Virus) infection)

Phenothiazine neuroleptics (used in the treatment of severe mental illness/schizophrenia)

Thyroid hormones (used in the treatment of thyroid gland diseases and dysfunctions)

Salicylates and diflunisal (used for fever or pain)

Chloroquine and proguanil (used for malaria treatment)

Digoxin (used in the treatment of heart diseases)

Estramustine (used in the treatment of prostate cancer)

Fexofenadine (used for allergy symptoms)

Fluoride (used in the prevention of tooth decay)

Indomethacin (Non-steroidal anti-inflammatory drug / used in the treatment of inflammation)

Iron (used in the prevention and treatment of iron deficiency anemia)

Ledipasvir phosphate (used in hepatitis C disease)

Rosuvastatin (Statin group/used in cholesterol treatment)

Strontium (used in the treatment of bone loss)

Zinc (used in the treatment or prevention of zinc deficiency)

Sodium and calcium polystyrene sulfonate and resins (used in the treatment of high potassium in the blood)

Teriflunomide (used in the treatment of a disease called multiple sclerosis, which occurs as a result of a disorder in the immune system, leading to the formation of many plaques in the brain and spinal cord)

Levothyroxine (used in the treatment of thyroid gland diseases and dysfunctions)

Famotidine, an active ingredient in ACiDPASS, may reduce the absorption of atazanavir, rilpivirine (HIV medicine), most tyrosine kinase inhibitors (cancer medicine), and cyanocobalamin (for vitamin B12 deficiency) in the body.

The combination of famotidine and antacids may reduce the absorption of azole antifungals [(ketoconazole, itraconazole, posaconazole) used in fungal treatment] and ulipristal (emergency contraceptive medicine) in the body.

If you are currently using or have recently used any prescription or non-prescription medicine, please inform your doctor or pharmacist about them.

How to use ACiDPASS?

Instructions for proper use and dose / frequency of administration:

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (over 16 years):

If you experience heartburn or indigestion, chew one tablet thoroughly. If needed, drink a glass of water after chewing.

Do not take more than 2 tablets per day. Do not use for more than 2 weeks.

(See also section 2).

Route and method of administration:

ACiDPASS is for oral use only.

Different age groups

Use in children:

ACiDPASS is not recommended for use in children under 16 years of age.

Use in the elderly:

No dose adjustment is required.

Special use cases:

Kidney failure:

Should not be used in patients with severe kidney failure.

Liver failure:

If you have liver failure, consult your doctor before using this medicine.

If you have the impression that the effect of ACiDPASS is too strong or too weak, talk to your doctor or pharmacist.

If you have used more ACiDPASS than you should

If you have used more ACiDPASS chewable tablet than you should, contact your doctor or the nearest health institution, taking this leaflet with you.

If you have used more ACiDPASS than you should, talk to a doctor or pharmacist.

If you forget to use ACiDPASS

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with ACiDPASS is discontinued

No information available.

Possible side effects

Like all medicines, ACiDPASS can cause side effects in people who are sensitive to the substances contained in it. However, these side effects do not occur in everyone and are generally mild.

If any of the following occur, stop using ACiDPASS and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital:

Swelling of the face, tongue or throat that causes difficulty swallowing; hives and difficulty breathing (frequency unknown with available data).

Severe allergic reaction causing difficulty breathing or dizziness (frequency unknown with available data).

Severe and widespread skin damage (may start with painful regional redness, then end with large blisters and peeling of skin layers) (very rare)

These are all very serious side effects.

If you experience any of these, it means you have a serious allergy to ACiDPASS. You may need urgent medical attention or hospitalization.

All of these very serious side effects are quite rare.

Side effects are listed according to their frequencies as shown in the categories below:

Very common : May be seen in at least 1 in 10 patients.

Common : May be seen in less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon : May be seen in less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare : May be seen in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare : May be seen in less than 1 in 10,000 patients.

Unknown : Cannot be estimated from the available data.

Common

Headache

Uncommon

Nausea

Vomiting

Dizziness

Belching

Tingling and numbness

Diarrhea

Abdominal gas

Dry mouth

Abdominal bloating

Nervousness

Indigestion

Thirst

Abdominal pain

Taste disturbance

Abdominal distension

Discomfort and pain in the mouth, pharynx, and larynx

Unknown

Rash

Itching

Drowsiness

Hives

Unusual tiredness or weakness

Loss of energy

Swelling of the face and throat due to allergy

Pain in the upper abdomen

The following very rare side effects have been reported in people taking high doses of famotidine (one of the active ingredients in ACIDPASS).

Common

Headache, dizziness

Constipation, diarrhea

Uncommon

Loss of appetite, anorexia

Nausea, vomiting, abdominal pain or bloating, gas

Dry mouth

Rash, itching, urticaria (hives)

Fatigue

Taste disturbance

Rare

Slowdown or complete cessation of bile flow due to an obstruction in the bile ducts within the liver (intrahepatic cholestasis)

Enlargement of breasts in men (Gynecomastia)

Very rare

Somnolence (drowsiness, tendency to sleep)

Nervous system disorders such as hallucinations, mental confusion, difficulty sleeping (insomnia), lethargy, drowsiness, restlessness, and depression.

Significant decrease in platelet (blood cells)/red and/or white blood cell count/blood disorders.

Decrease in the number of defense cells in the blood (white blood cells) below a certain limit

A decrease in the number of white blood cells can reduce your resistance to infection. Therefore, if you observe a deterioration in your general condition or local infection symptoms such as a sore throat/larynx/mouth, or fever accompanied by problems in your urinary tract, inform your doctor immediately.

Severe allergic condition developing as a result of hypersensitivity (anaphylaxis), swelling of the face and throat due to allergy (angioneurotic edema), narrowing of the muscles surrounding the respiratory tract and bronchi causing shortness of breath (bronchospasm)

Reversible mental disorders including depression, nervousness, restlessness, impaired ability to adapt to the environment (disorientation), mental clouding, hallucinations (seeing, hearing or feeling things that are not there). These complaints usually disappear when the medication is discontinued.

Generalized tonic-clonic seizures (epileptic seizures) (especially in patients with kidney failure), paresthesia (impaired perception of tactile sensation), seizures

Heart rate irregularities such as atrioventricular block as a result of intravenous administration of H2 receptor antagonists, the drug group to which ACIDPASS belongs.

Lung infection (pneumonia), which can sometimes be severe

Feeling of tightness in the chest

Abnormalities in liver enzymes, jaundice, hepatitis (an inflammation of the liver)

Muscle cramps, joint pain

Stevens-Johnson Syndrome (a condition where the skin and mucous membranes react severely to medication or

infection)/severe skin reactions called toxic epidermal necrolysis, sometimes fatal

Impotence

Alopecia (hair loss).

Changes in stool frequency and consistency and bloating, a feeling of fullness, may occur due to the antacids (magnesium hydroxide and calcium carbonate) contained in ACİDPASS.

If you experience any side effects not mentioned in this package leaflet, inform your doctor or pharmacist.

Reporting of side effects:

If you experience any side effects, whether or not listed in the Package Leaflet, talk to your doctor, pharmacist or nurse. You can also contribute to obtaining more information about the safety of the medicine you are using by reporting the side effects you encounter to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Notification" icon on www.titck.gov.tr or by calling the side effect notification line 0800 314 00 08.

How to store ACİDPASS?

Keep ACİDPASS out of the sight and reach of children and in its original packaging.

Store at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use ACİDPASS after the expiry date stated on the packaging.

Do not use ACİDPASS if you notice any defects in the product and/or its packaging.

Disposal:

Do not throw away expired or unused medicines into waste water! Give them to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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This package leaflet was approved on