

Cafergot

Ergotamine tartrate 1 mg and Caffeine 100 mg Tablets

What is in this leaflet

Please read this leaflet carefully before you start taking Cafergot.

This leaflet answers some common questions about Cafergot tablets

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Cafergot against the benefits it can provide.

If you have any concerns about Cafergot, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What Cafergot is used for

Cafergot is used to treat attacks of migraine with or without aura.

These headaches are thought to be caused by temporary changes in the size of small blood vessels in the brain. These blood vessels swell, causing the pain and visual disturbances that often happen during an attack. Cafergot stops the attack by causing the blood vessels to constrict (shrink) back to normal size.

Cafergot is only taken to treat migraine attacks. It is not taken to prevent attacks from happening.

There are some types of headaches which must not be treated with Cafergot. Your doctor will determine the best treatment for your headache.

Cafergot tablets contain the active ingredients, ergotamine tartrate and caffeine. Ergotamine belongs to a group of medicines known as the "ergot alkaloids." Caffeine helps ergotamine work better and faster by increasing its absorption into the body.

Ask your doctor if you have any questions about why Cafergot has been prescribed for you.

Your doctor may have prescribed Cafergot for another reason.

Cafergot is only available with a doctor's prescription.

There is not enough information to recommend this medicine for children under 6 years of age.

Before you take Cafergot

When you must not take Cafergot

Do not take Cafergot if you have ever had an allergic reaction to any of the following:

- ergotamine or caffeine, the active ingredients in Cafergot tablets
- any of the other ingredients listed at the end of this leaflet
- any other ergot alkaloids (e.g. Ergodryl[®], Ergometrine[®], Syntometrine[®]).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Cafergot if you have any of the following health problems/medical conditions:

- problems with your heart, especially if you have angina that is not controlled or you have had a heart attack
- high blood pressure that is not controlled
- severe liver or kidney disease
- poor blood circulation or other blood vessel disorders (e.g. varicose veins, fluid buildup in legs or feet, or conditions that make your fingers and toes unusually sensitive to cold)
- you are being treated with mexiletine (a medicine for irregular heartbeats)
- you are being treated with fluvoxamine (a medicine for mental disorder)
- you are being treated for cough and cold or increased weight with medicines such as phenylephrine, amphetamine, cocaine or phentermine
- a serious infection
- you are being treated for HIV/AIDS with a medicine called ritonavir, nelfinavir, indinavir or delavirdine
- you are taking a contraceptive pill to prevent pregnancy
- you are being treated for an infection with a medicine called ketoconazole, itraconazole, erythromycin, clarithromycin, quinupristin, dalfopristim, ciprofloxacin, norfloxacin

When previously treated with ergotamine derivative, if you had developed scarring and thickening of any of the following: the abdominal cavity, lungs tissue or lining that surrounds the lungs, heart tissue or lining that surrounds the heart, do not take this medicine.

Do not take Cafergot if you are pregnant or intend to become pregnant.

This medicine may affect your developing baby if you take it while you are pregnant.

Do not breast-feed if you are using Cafergot.

The active ingredients in Cafergot may pass into breast milk and may affect your baby.

Do not take Cafergot after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take Cafergot

Tell your doctor if you smoke.

Nicotine in cigarettes may increase the chance of you having an unwanted side effect called "ergotism" (excessive constriction of blood vessels). See Side Effects section for more information.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food store. You should also tell your health professional who is prescribing a new medication for you that you are taking Cafergot.

Some medicines and Cafergot may interfere with each other. These include:

- some medicines used to treat HIV/AIDS, including ritonavir, nelfinavir, indinavir, delavirdine, saquinavir or nevirapine
- some medicines for infections, including ketoconazole, itraconazole, fluconazole, voriconazole, clotrimazole, rifampicin, erythromycin, clarithromycin, troleandomycin, quinupristin, dalfopristin, ciprofloxacin, norfloxacin, ofloxacin
- some medicines used to treat mental disorders, including nefazodone, fluoxetine, fluvoxamine, amitriptyline, sertraline
- zileuton, a medicine used to prevent asthma attacks
- mexiletene, a medicine used to treat irregular heartbeats
- other ergot alkaloids
- oral contraceptives
- other medicines used to treat migraine such as sumatriptan
- nicotine in medicines used to help you quit smoking, such as nicotine patches or chewing gum
- some medicines for cough and cold or increased weight such as phenylephrine, amphetamine, cocaine or phentermine
- beta-blocker medicines such as propranolol, which are used to prevent migraine and also to treat heart problems and high blood pressure
- any other medicine that can cause blood vessels to contract (shrink).

You may need to take different amounts of your medicines or to take different medicines while you are taking Cafergot. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking Cafergot.

How to use Cafergot

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults

At the first sign of a migraine attack, swallow two Cafergot tablets.

This dose is usually enough to stop an attack but, if the migraine doesn't go away, you can have another dose every half an hour to a maximum of 6 tablets in one day.

Do not take more than 6 tablets in one day.

Do not take more than 10 tablets in one week.

Children

At the first sign of a migraine attack, swallow one Cafergot tablet.

This dose is usually enough to stop an attack but, if the migraine doesn't go away, you can have another dose every half an hour to a maximum of 3 tablets in one day.

Do not take more than 5 tablets in one week.

If you take too much Cafergot or if you take it too often, you may have an increased risk of serious side effects such as "ergotism" or retroperitoneal or pleuropulmonary fibrosis (see Side Effects section for more information). You may also have side effects such as headaches, tiredness, runny nose and muscle pain when you stop using it.

Do not take sumatriptan, zolmitriptan or naratriptan or any medicine containing ergot alkaloids (e.g. Dihydergot[®] or Ergodryl[®]) at the same time as you take Cafergot.

If you wish to take one of these other medicines following a dose of Cafergot, your doctor or pharmacist can advise you how long to wait before you take it.

Things you must do while taking Cafergot

If you become pregnant while using Cafergot, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Cafergot.

Tell any other doctor, dentist or pharmacist who treats you that you are using Cafergot.

Things you must not do

Do not take Cafergot to prevent a migraine attack from happening.

This medicine should only be taken to treat a migraine once it has started.

Avoid drinking grapefruit juice while you are using Cafergot.

Grapefruit juice may interfere with the action of Cafergot in your body.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not take it to treat any other complaints unless your doctor tells you to.

This medicine is not appropriate for common 'tension' headaches.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Cafergot affects you.

This medicine may cause dizziness or vertigo (spinning sensation) in some people. Make sure you know how it affects you before you drive a car, operate machinery, or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cafergot, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Stop using Cafergot and tell your doctor immediately if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; wheezing or troubled breathing
- signs of "ergotism" (excessive constriction of blood vessels) such as numbness, coldness, tingling or a pale or bluish colour in the fingers or toes, pain or spasms in muscles, chest pain
- pain in the lower back or side, associated with difficulty in passing urine or pain on urinating, which may be a sign of retroperitoneal fibrosis, a thickening of the abdominal lining that can cause obstruction of the urinary tract
- shortness of breath, dry cough, pain in the chest or rib area, which may be a sign

- of pleuropulmonary fibrosis, a scarring and thickening of lung tissue
- chest pain as this may be a sign of too little blood and oxygen getting to the heart muscle or in rare cases, a heart attack.
- you feel faint or look pale, which could be signs of shock

The above are serious side effects that need medical attention.

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling sick) or vomiting
- stomach pain
- diarrhoea
- dizziness
- dull headaches
- Intensifying headache with autonomic disturbances after Cafergot withdrawal
- fast, slow or irregular heart beat
- increase in your blood pressure
- muscular pain or spasm
- pain or weakness in your arms or legs

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

Overdose

Immediately telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre, Dunedin (telephone 0800 POISON OR 0800 764 766), or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Cafergot. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include nausea, vomiting, fast heart-beat, numbness or tingling in the fingers and toes, abnormal blue discoloration of the skin and mucous membranes, weak pulse, dizziness, drowsiness, confusion, difficulty breathing, low blood pressure, fits and coma.

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool place where the temperature stays below 25°C.
- Do not store Cafergot or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Cafergot or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Other ingredients

Cafergot tablets also contain the following inactive ingredients:

- tartaric acid
- magnesium stearic
- purified talc
- maize starch
- cellulose, microcrystalline
- iron oxide yellow (E172)
- talc

If you want to know more

Talk to your doctor or pharmacist. They will be able to answer your questions.

Distributor

Cafergot is supplied in New Zealand by:
AFT Pharmaceuticals Ltd.
PO Box 33.203
Takapuna
AUCKLAND

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