

Cafergot(R)

ergotamine tartrate / caffeine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cafergot tablets and Cafergot S suppositories.

It does not contain all the available information. It does not take the place of talking to your doctor and 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 this medicine, 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 and other similar "vascular" headaches.

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 used to treat migraine attacks. It is not used 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 and Cafergot S suppositories 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Cafergot is only available with a doctor's prescription.

There is not enough information to recommend this medicine for children under 12 years of age.

Before you use Cafergot

When you must not use it

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

- * ergotamine or caffeine, the active ingredients in Cafergot tablets and Cafergot S suppositories
- * any of the other ingredients listed at the end of this leaflet
- * any other ergot alkaloids (e.g. Deseril(R), Dihydergot(R), Ergodryl(R), Ergometrine(R), Kripton(R), Parlodel(R), Syntometrine(R)).

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 use 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
- * 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)
- * a serious infection
- * you are being treated for HIV/AIDS with a medicine called ritonavir, nelfinavir, indinavir or delavirdine
- * you are being treated for an infection with a medicine called ketoconazole, itraconazole, erythromycin or clarithromycin

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

This medicine may affect your developing baby if you use 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 use 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 use it

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 lactose intolerant.

Cafergot tablets contain lactose.

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.

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

- * some medicines used to treat HIV/AIDS, including ritonavir, nelfinavir, indinavir, saquinavir
- * some medicines for infections, including ketoconazole, itraconazole, fluconazole, clotrimazole, erythromycin, clarithromycin
- * some medicines used to treat mental disorders, including nefazodone, fluoxetine, fluvoxamine
- * other ergot alkaloids
- * other medicines used to treat migraine such as sumatriptan, naratriptan and zolmitriptan
- * nicotine in medicines used to help you quit smoking, such as nicotine patches or chewing gum

- * 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 using 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 using this medicine.

How to use Cafergot

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

These instructions 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.

How much to use

At the first sign of a migraine attack, swallow two Cafergot tablets or insert one Cafergot S suppository into your rectum (back passage).

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 or 3 suppositories in one day.

Do not take more than 6 tablets or use more than 3 suppositories in one day.

Do not take more than 10 tablets or use more than 5 suppositories in one week.

If you use too much Cafergot or if you use 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 use sumatriptan, zolmitriptan or naratriptan or any medicine containing ergot alkaloids (e.g. Dihydroergot(R) or Ergodryl(R)) at the same time as you use Cafergot.

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

If you use too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used 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 vomiting, diarrhoea, thirst, fast heart-beat, chest pain, weak pulse, coldness or itching of the skin, numbness or tingling in the fingers and toes, dizziness, drowsiness, confusion, difficulty breathing and fits.

While you are using Cafergot

Things you must do

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 use 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 use 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 using 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, weakness in the lower legs, 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
- * fast, slow or irregular heart beat
- * irritation or bleeding of the rectum after use of the suppository

- * increase in your blood pressure
- * muscular pain
- * 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.

After using Cafergot

Storage

- * Keep your medicine in the original container until it is time to use it.
- * Store it in a cool place where the temperature stays below 25 degrees 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 the 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.

Product description

What it looks like

Cafergot tablets are white, round, sugar-coated tablets with no markings on them; packs of 20 tablets.

Cafergot S suppositories are whitish or with a tinge of grey/pink; packs of 5 suppositories.

Ingredients

Cafergot tablets contain 1 mg of ergotamine tartrate and 100 mg of caffeine. They also contain the following inactive ingredients:

- * tartaric acid
- * gelatin
- * stearic acid
- * purified talc
- * maize starch
- * colloidal anhydrous silica
- * acacia
- * sucrose
- * lactose
- * titanium dioxide

Cafergot S suppositories contain 2 mg of ergotamine tartrate and 100 mg of caffeine. They also contain the following inactive ingredients:

- * tartaric acid
- * lactose
- * hard fat suppository base

Sponsor

Cafergot tablets and Cafergot S suppositories are supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited
ACN 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203

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