

CAFERGOT TABLET

Ergotamine Tartrate / Caffeine (1mg/100mg)

What is in this leaflet

1. What cafergot is used for
2. How cafergot works
3. Before you use cafergot
4. How to use cafergot
5. While you are using it
6. Side effects
7. Storage and disposal of cafergot
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What cafergot is used for

Cafergot is used to treat acute attacks of migraine and related types of headache (vascular headache)

How cafergot works

Cafergot contains 2 active ingredients which are ergotamine tartrate and caffeine. 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.

Before you use cafergot

Tell your doctor if you smoke.

Nicotine in cigarettes may increase the chance of you having an unwanted side effect called enhanced vasoconstriction (excessive constriction of blood vessels).

- When you must not use it

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

- a) ergotamine or caffeine, the active ingredients in Cafergot tablets
b) any of the other ingredients listed at the end of this leaflet
-any other ergot alkaloids

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

- a) problems with your heart, especially if you have chest pain that is not controlled or you have had a heart attack.
- b) high blood pressure that is not controlled liver or kidney disease
- c) poor blood circulation or other blood vessel disorders.
- d) a serious infection
- e) temporal arteritis (inflammatory disease of the blood vessel)
- f) Rare and serious type of migraine
- g) you are being treated for HIV/AIDS with medicine called HIV protease or reverse transcriptase inhibitors
- i) you are being treated for an infection with a medicine called macrolide or azole
- j) you are being treated with other migraine medicines such as ergot alkaloids, sumatriptan or other 5HT1 receptor agonists

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.

- 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:

- a) some medicines used to treat HIV/AIDS including HIV protease or reverse transcriptase inhibitors (e.g. ritonavir, indinavir, nelfinavir, delavirdine)
- b) some medicines for infections, including macrolide or azoles antibiotics (e.g. erythromycin, clarithromycin, ketoconazole, itaconazole, voriconazole)
- c) other ergot alkaloids
- d) other medicines used to treat migraine such as sumatriptan
- e) beta-blocker medicines such as propranolol, which are used to prevent migraine and also to treat heart problems and high blood pressure

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.

CAFERGOT TABLET

Ergotamine Tartarate / Caffeine (1mg/100mg)

How to use Cafergot

- How much to use

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.

The first time Cafergot is taken, an initial dose of 2 Cafergot tablets orally is recommended.

If relief is not obtained within half an hour, a further tablet should be administered; this may be repeated at half-hourly intervals, but the maximum daily dose indicated should not be exceeded.

For subsequent attacks, the initial dose may be increased to 3 tablets, depending on the total dose required in previous attacks. If pain persists, additional dose of 1 tablet may be taken at half hourly intervals up to maximum dose.

Maximum dose per attack or per day

Adults: 6 tablets

Maximum weekly dose

Adults: 10 tablets

- When to use it

You should take Cafergot at the first symptoms of an attack.

- How long to use it

Cafergot is only taken when you have migraine attacks. Do not exceed the maximum dose.

- If you forget to use it

If you forget to take Cafergot, take the dose as soon as you remembered. If it is almost time for the next dose, ignore the

forgotten dose and take the next dose as per scheduled. Do not double the dose to replace the dose that you have forgotten to take.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause: Nausea, vomiting, drowsiness, confusion, numbness, tingling and pain in the extremities due to ischaemia (blockage of blood supply), respiratory depression, coma.

While you are using it

- Things you must do

Tell your doctor if you are pregnant, or may be pregnant

- Things you must not do

- Patients experiencing dizziness should not drive or operate machinery.

Things to be careful of

- Cafergot is only indicated for the treatment of acute migraine attacks but not for prevention.
- Consecutive daily use and excess use than the recommended doses may cause vasospasm (sudden constriction of blood vessel).
- If ergotamine containing drugs including cafergot are used excessively over years, they may induce formation of excess connective tissue in an organ.

- *Ergotamine* may cause myocardial ischaemia (reduced blood flow to the heart), or in rare cases, infarction (heart attack), even in patients with no known history of coronary heart disease.
- The occurrence of drug-induced headaches has been reported during prolonged and uninterrupted treatment with Cafergot

Side effects

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.

The side effects of Cafergot are listed below:

- a) Nausea
- b) Vomiting
- c) The constriction of blood vessels, which increases blood pressure.
- d) Dizziness
- e) Abdominal pain
- f) Hypersensitivity reactions

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

- a) 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
- b) first symptoms of overdose: paresthesia (e.g. numbness, tingling) in the fingers and toes, non migraine related nausea or vomiting, and symptoms of heart attack.

CAFERGOT TABLET

Ergotamine Tartrate / Caffeine (1mg/100mg)

If ergotamine containing medicines are used extensively over years, they might cause lungs, kidneys, pancreas or formation of excess connective tissue in heart valves. Please ask your doctor for more information about this side effect.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you do not understand anything in this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of cafergot

- Storage

- Keep out of reach and sight of children
- Keep cafergot below 25°C.
- Do not use cafergot after the expiry date which is printed on the carton
- Protect from light.

- 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

- Cafergot is circular, flat, speckled yellowish-white tablets with isolated dots of pigment and bevelled edges. One side of cafergot bears the imprint “XL” and a score line, while it is plain on the other side. Cafergot are packed 20 tablets in a bottle.
- Each table contains 1mg ergotamine tartrate and 100mg caffeine.

- Ingredients

- Active ingredients
1mg ergotamine tartrate
100mg caffeine
- Inactive ingredients
Tartaric acid;
Cellulose,
microcrystalline;
Iron oxide yellow;
Talc;
Magnesium stearate

- MAL number

MAL13035053ACZ

Manufacturer

Cenexi SAS,
52, Rue Marcel et Jacques
Gaucher, 94120 Fontenay-
Sous-Bios, France.

Product Registration

Holder

A.Menarini Singapore Pte.
Ltd.
B-18-2, Level 18, The Ascent
Paradigm,
No 1, Jalan SS 7/26A, Kelana
Jaya, 47301
Petaling Jaya, Selangor Darul
Ehsan, Malaysia

Date of Revision

28/07/2017

Serial Number

NPRA(R4/1)030817/00191