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**PATIENT INFORMATION LEAFLET**

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**Cafergot<sup>®</sup> Suppositories 2 mg**  
ergotamine tartrate and caffeine

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**Read all of this leaflet carefully before you start using this medicine**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

- 1. What Cafergot Suppositories are and what they are used for**
- 2. Check before you use Cafergot Suppositories**
- 3. How to use Cafergot Suppositories**
- 4. Possible side effects**
- 5. How to store Cafergot Suppositories**
- 6. Further information**

**1. What Cafergot Suppositories are and what they are used for**

Cafergot Suppositories belong to a group of medicines called antimigraine drugs.

Cafergot Suppositories are for insertion into the back passage (rectum).

Cafergot Suppositories are used to treat migraines which have not responded to simple painkillers. They are used at the first sign of a migraine attack to relieve the symptoms and to stop the attack getting worse.

Do not use Cafergot Suppositories to prevent migraine attacks.

**2. Check before you use Cafergot Suppositories****Do not use Cafergot Suppositories if you:**

- are allergic (hypersensitive) to ergotamine tartrate, caffeine or any of the ingredients of Cafergot Suppositories (see section 6 Further information)
- have poor blood circulation to your arms and legs
- suffer from heart problems

- have high blood pressure which has not been controlled by treatment
- are suffering from a severe infection (septic shock)
- suffer from kidney problems
- suffer from liver disease
- suffer from a condition known as giant cell arteritis or temporal arteritis (the symptoms of which can include severe headache, a tender scalp and problems with your vision)
- suffer from a specific type of migraine called a basilar migraine (symptoms of which include giddiness, double vision, unsteadiness, fainting or loss of consciousness) or a hemiplegic migraine (symptoms of which include temporary paralysis down one side of the body, hearing impairment, numbness around the mouth leading to trouble speaking or swallowing)
- are pregnant or breast-feeding
- are taking a certain type of antibiotics (called macrolides) for example, erythromycin, clarithromycin, azithromycin
- are taking medicines to treat HIV or AIDS (called HIV-protease or reverse-transcriptase inhibitors) for example, amprenavir, indinavir
- are taking certain types of antifungals (called azole antifungals) for example, ketoconazole, miconazole
- are taking other anti-migraine drugs (including ergot alkaloids or drugs that end in 'triptan' such as sumatriptan, almotriptan, rizatriptan).

Do not give Cafergot Suppositories to children under 12 years old.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Cafergot Suppositories.

### **Take special care with Cafergot Suppositories**

Before you use Cafergot Suppositories tell your doctor if:

- you have taken a triptan (such as almotriptan, rizatriptan, sumatriptan or zolmitriptan) in the last 6 hours
- you are a smoker.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Cafergot Suppositories.

If you attend hospital, or are about to have an operation or medical procedure tell the medical staff that you use Cafergot Suppositories.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines as they may interfere with Cafergot Suppositories:

- antibiotics - used to treat bacterial infections such as macrolides (for example, erythromycin, azithromycin, clarithromycin, spiramycin, telithromycin), quinupristin, dalfopristin, tetracycline
- antifungals - used to treat fungal infections such as, ketoconazole, miconazole, itraconazole, posaconazole, voriconazole
- antivirals - used to treat HIV infection such as amprenavir, indinavir, nelfinavir, ritonavir, saquinavir, atazanavir, efavirenz
- 5HT<sub>1</sub> agonists (triptans) - used to treat migraines such as almotriptan, rizatriptan, sumatriptan, zolmitriptan, eletriptan, frovatriptan
- cimetidine - used to treat stomach ulcers and heartburn
- treatments for low blood pressure for example ephedrine hydrochloride, metaraminol
- beta-blockers - used to treat heart disease, angina and other heart disorders such as propranolol, oxprenolol, atenolol
- nicotine - for example from smoking or nicotine replacement therapy (nicotine patches or gum)
- certain general anaesthetics - for example halothane
- certain antidepressants - for example reboxetine.

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

### **Pregnancy and breast-feeding**

Do not use Cafergot Suppositories if you are pregnant or breast-feeding. Cafergot Suppositories can be passed into breast milk and may cause vomiting, diarrhoea, changes in blood pressure and a weak heartbeat in your baby. If you become pregnant whilst using Cafergot Suppositories tell your doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Cafergot Suppositories may make you dizzy or anxious. If you are affected do not drive or operate machinery until these effects have worn off.

### **3. How to use Cafergot Suppositories**

Always use Cafergot Suppositories exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

#### **Adults and the Elderly**

Cafergot Suppositories should be inserted into the back passage (rectum). The usual dosage is one suppository used at the first sign of a migraine attack. Your doctor may increase your dose to two suppositories in 24 hours, however it is important to use the lowest dose which is effective.

Keep a record of how many suppositories you use.  
It is important that you:

- do not use more than 2 Cafergot Suppositories in 24 hours
- do not use Cafergot Suppositories every day to prevent migraines
- do not use Cafergot Suppositories if you have already used a course of treatment within the last 4 days
- do not use more than 4 Cafergot Suppositories in a week

If you are not getting relief from your migraine do not use more suppositories, tell your doctor.

#### **Children**

Do not give Cafergot Suppositories to children under 12 years old.

#### **What to do if you use more Cafergot Suppositories than you should**

If you accidentally use too many Cafergot Suppositories or someone else uses any of your medicine, you should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

Symptoms of an overdose include feeling or being sick, drowsiness, dizziness or confusion, having a slow or fast heartbeat, difficulty breathing, convulsions, tingling or numbness in your fingers or toes, your fingers turning blue, difficulty in passing urine or severe headache.

#### **If you forget to use Cafergot Suppositories**

Do not worry. If you forget to use a dose, use it as soon as possible, unless it is almost time to use the next dose. Do not use a double dose. Then go on as before.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Do not worry. Like all medicines, Cafergot Suppositories can cause side effects, although not everyone gets them.

If you experience severe numbness or tingling in your hands or feet, nausea, vomiting, pains in your chest or are passing less urine than normal, stop taking Cafergot Suppositories and contact a doctor or go to the nearest hospital straight away as you may need urgent medical attention.

Common side effects (that affect less than 1 person in 10):

- feeling or actually being sick
- stomach pain
- dizziness.

Uncommon side effects (that affect less than 1 person in 100):

- poor circulation in your hands or feet which can make them feel cold or painful and look pale or blue
- pain or weakness in your arms, hands, legs or feet
- tingling or numbness in your hands or feet
- diarrhoea.

Rare side effects (that affect less than 1 person in 1000):

- allergic reactions that may include itchy rash, swelling of the face, difficulty breathing, nettle rash
- slow or fast heartbeat
- high blood pressure
- muscle pain
- headache
- stroke (causing sudden weakness or numbness, dizziness or severe headache)
- changes in blood tests which show how the kidneys are working.

Very rare side effects (that affect less than 1 person in 10 000):

- angina or heart attack (causing pain in the chest)
- gangrene (when the blood supply to extremities such as toes or fingers is cut off).

The caffeine in Cafergot Suppositories may cause the following unwanted side effects:

- feeling of anxiety

- trembling
- sweating
- fast heartbeat.

Cafergot Suppositories sometimes cause the following side effects in some people:

- rectal and anal ulcers.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. How to store Cafergot Suppositories**

Keep out of the reach and sight of children.

Do not use Cafergot Suppositories after the expiry date which is stated on the carton (EXPIRY). The expiry date refers to the last day of that month.

Do not store above 25°C

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

## **6. Further information**

### **What is in Cafergot Suppositories?**

The active ingredients in this medicine are ergotamine tartrate and caffeine. The other ingredients are: tartaric acid, lactose and supocire AM.

### **What Cafergot Suppositories look like and contents of the pack**

Cafergot Suppositories are off-white suppositories.

Cafergot Suppositories come in packs of 30.

### **Marketing Authorisation Holder and Manufacturer**

The product licence holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Cafergot Suppositories are manufactured by: Novartis Pharmaceuticals Ltd, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, UK.

The information in this leaflet applies only to Cafergot Suppositories. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

**This leaflet was last approved:** 30<sup>th</sup> March 2009

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