Package leaflet: Information for the patient

Cufence 200 mg hard capsules
trientine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cufence is and what it is used for
2. What you need to know before you take Cufence
3. How to take Cufence
4. Possible side effects
5. How to store Cufence
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1. What Cufence is and what it is used for

Cufence is a medicine used for the treatment of Wilson's disease in adults, adolescents and children aged 5 years or older. It is for use by patients who cannot take another medicine, D-Penicillamine, because of side effects.

Cufence contains the active substance trientine, a copper-chelating agent that is used to remove excess of copper from the body. Cufence attaches to the copper, which is then passed from the body.

2. What you need to know before you take Cufence

Do not take Cufence:

If you are allergic to trientine or any of the other ingredients of this medicine (listed in section 6).

Signs of an allergic reaction include rash, itching, swelling of the face, fainting and breathing problems.

Warnings and precautions

Your doctor will need to regularly check for symptoms of the disease and copper levels in your blood and urine. Regular monitoring is especially important at the start of your treatment or when your dose is changed, in growing children and pregnant women to ensure that copper levels are maintained at a suitable level. The doctor may need to increase or decrease your dose of Cufence.

Nervous system problems can occur (for example, shaking, lack of coordination, slurred speech, muscle stiffness and worsening of muscle spasms), especially in patients just starting treatment with Cufence. If you notice these whilst taking Cufence, you must tell your doctor immediately.

Lupus-like reactions (symptoms may include persistent rash, fever, joint pain, and tiredness) have been reported in some patients switched to trientine medicine after penicillamine medicine. However it

was not possible to determine if the reaction was due to trientine or to previous penicillamine treatment.

Other medicines and Cufence

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking iron tablets or medicines that neutralise the acid in your stomach, leave at least 2 hours before or after you have taken Cufence because they may reduce Cufence's effect.

Cufence with food and drink

Take this medicine with water only. Do not take it with other drinks or food because they may reduce the medicine's effect. Avoid eating or drinking for 1 hour before, or 2 hours after taking Cufence.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is very important to continue treatment to maintain normal copper levels during pregnancy. You and your doctor should fully discuss the potential benefits of treatment whilst considering any possible risks that there may be. Your doctor will advise you which treatment and which dose is best in your situation. If you become pregnant whilst taking Cufence, talk to your doctor.

If you are pregnant and taking Cufence, you will be monitored throughout your pregnancy for any effects on the baby or changes in your copper levels.

The limited information available suggests that Cufence does not pass into breast milk, but it is not certain that there is no risk to the baby. It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or to stop taking Cufence, considering the benefit of breast-feeding to the baby and the benefit of Cufence to the mother. Your doctor will decide which treatment and which dose is best in your situation.

Driving and using machines

Trientine is not likely to have an effect on your ability to drive or use machines.

3. How to take Cufence

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

Adults (including the elderly)

The usual dose is between 4 and 8 capsules per day, to be taken by mouth.

Use in children and adolescents (5 to 17 years)

In children and adolescents, the dose depends on age and body weight and will be adjusted by your doctor. At the start of treatment the dose varies between 2 and 5 capsules per day.

Method of administration

Your doctor will decide the correct dose for you.

The total daily dose can be divided into 2 to 4 smaller doses, as indicated by your doctor. Swallow the capsules whole with a drink of water on an empty stomach, at least 1 hour before or 2 hours after food.

Patients who have difficulties swallowing should contact their doctor.

If you take more Cufence than you should

If you take more medicine than you should, you may get nausea, vomiting and dizziness. You must contact your doctor or another health care provider immediately.

If you forget to take Cufence

If you forget to take a dose take your next dose at its usual scheduled time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Cufence

This medicine is for long-term use because Wilson's disease is a life-long condition. Do not stop or change your treatment without speaking with your doctor even if you feel better.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Occasionally (*frequency unknown; cannot be estimated from available data*), treatment with this medicine can cause inflammation of the small intestine or colon. If you have any of the following side effects contact your doctor **immediately**:
- Severe stomach pains
- Persistent diarrhoea
- Nervous system problems (for example shaking, lack of coordination, slurred speech, muscle stiffness, worsening of muscle spasms).

Other side effects may include:
Common (may affect up to 1 in 10 people)
- Nausea (especially when starting treatment)

Uncommon (may affect up to 1 in 100 people)
- Skin rashes
- Anaemia (you may feel unusually tired)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Cufence

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date which is stated on the bottle label and outer carton. The expiry date refers to the last day of the month.

Use within 3 months after first opening the bottle. Do not use if the capsules become sticky or wet. Store in the original container in order to protect from moisture. Store in a refrigerator (2ºC-8ºC). Do not freeze.

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.

6. Contents of the pack and other information

What Cufence contains

- The active substance is trientine. Each capsule contains 300 mg trientine dihydrochloride, equivalent to 200 mg trientine.
- The other ingredients are
  Capsule content:
  Magnesium stearate
  Colloidal anhydrous silica

  Capsule shell:
  Gelatin
  Titanium dioxide (E171)

  Printing ink:
  Shellac
  Propylene glycol
  Titanium dioxide (E171)
  Iron oxide black (E172)
  Iron oxide yellow (E172)

What Cufence looks like and contents of the pack

Amber glass bottle with a polypropylene cap and induction heat seal liner with a sachet of dried silica gel as desiccant. Each hard capsule is white, oval-shaped size 0 with Cufence 200 printed in grey ink.

Pack size: one bottle of 100 hard capsules.

Marketing Authorisation Holder
Univar BV
Schouwburgplein 30-34
3012 CL Rotterdam
The Netherlands

Manufacturer
Aesica Pharmaceuticals GmbH
Alfred-Nobel Strasse 10
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This leaflet was last revised in 07/2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.There are also links to other websites about rare diseases and treatments.