

Ceretam

Ceretam 800mg Film-Coated Tablet
Ceretam Oral Solution 20%w/v

Piracetam 800mg
 Each 5ml contains piracetam 1g

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1. What Ceretam is used for

- Treatment of the elderly with some degree of cerebral functional impairment such as loss of memory, a lack of concentration or alertness and feeling of dizziness.
- Ceretam is indicated for patients suffering from myoclonus of cortical origin, irrespective of aetiology (cause) and should be used in combination with other anti-myoclonic therapies.

2. How Ceretam works

Ceretam contains active ingredient Piracetam. Piracetam acts on the brain and the nervous system and is thought to protect it against shortness of oxygen. Ceretam is used in combination with other medicines to treat myoclonus. This is a condition causing muscles, particularly in the arms and legs, to start jerk or twitch uncontrollably.

3. Before you use Ceretam

When you must not use it

- If you are allergic to the active ingredient piracetam, other pyrrolidone derivatives or to other ingredients of Ceretam Tablet
- If you have ever had serious kidney problems.
- If you suffer from Huntington's Chorea (an inherited disease that causes progressive breakdown of nerve cells in the brain which causes involuntary movements).
- If you have ever experienced a brain haemorrhage(bleeding).

-Before you start to use it

Check with your doctor

- If you think your kidney may not be working perfectly

- You have ever had any kind of bleeding problem.

-Taking another medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop:

- Thyroid hormones
- Acenocoumarol
- Antiepileptic drugs
- Alcohol
- Any other medicines, including medicines obtained without prescription.

-Pregnancy and breast-feeding

- **Pregnancy:** There is no adequate data from the use of piracetam in pregnant women. Piracetam crosses the placental barrier. Drug levels in the newborn are approximately 70% to 90% of maternal levels. Piracetam should not be used during pregnancy unless clearly necessary, when benefit exceeds the risks and the clinical condition of the pregnant mother requires treatment with piracetam.
- **Breast-feeding:** Piracetam is excreted in human breast milk. Therefore, piracetam should not be used during breastfeeding or breastfeeding should be discontinued, while receiving treatment with piracetam. A decision must be made whether to discontinue breast-feeding or to discontinue piracetam therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Driving and using machines

Ceretam may cause drowsiness and shakiness. If this happens to you, do not drive or use machinery.

4. How to use Ceretam

-How much to use it

- The amount of Ceretam tablets to be taken varies depending on the treatment.
- The recommended starting dose for adults is 7.2g each day.
- It is best to split the dose so that the tablets are taken in two to four

divided doses during the day with a maximum dose of 24 g per day.

- Follow your doctor's instruction carefully.
- If you are elderly or have kidney problems your doctor may reduce your dose

-When to use it

- Ceretam should be swallowed whole with water, and do not break or chew the tablets as piracetam has a very bitter taste.
- Try to take your medicine at the same time every day.
- If you find it difficult to swallow the tablets, tell your doctor as they can prescribe piracetam in the form of solution.
- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

-How long to use it

The duration of treatment is determined by your doctor.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use overdose

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if 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.

5. While you are using Ceretam

-Thing you must do

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist

-Things you must not do

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.

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-Things to be careful of

Do not stop taking Ceretam without first talking to your doctor.

6. Side Effects of Ceretam Tablet

Ceretam may cause side effects to patients, Undesirable effects are listed in the following table per System Organ Class and per frequency. The frequency is defined as follows: very common; common; uncommon; rare; very rare.

• Blood and lymphatic system disorders

Not known: haemorrhagic (bleeding) disorder

• Immune system disorders

Not known: anaphylactoid reaction (reaction that produces the same clinical picture with serious allergic reaction but are not mediated by IgE which is a type of antibody), hypersensitivity.

• Psychiatric disorders

Common: nervousness;
 Uncommon: depression;
 Not known: agitation, anxiety, confusion, hallucination.

• Nervous system disorders

Common: hyperkinesia (muscle spasm); Uncommon: somnolence (sleepiness)
 Not known: ataxia (degenerative disease of nervous system), balance impaired, epilepsy aggravated, headache, insomnia.

• Ear and Labyrinth disorders

Not known: vertigo (spinning dizziness)

• Gastrointestinal disorders

Not known: abdominal pain, abdominal pain upper, diarrhoea, nausea, vomiting.

• Skin and subcutaneous tissue disorders

Not known: angioneurotic oedema (a subcutaneous form of hives), dermatitis (skin irritation), pruritus (severe itching of skin), urticarial (hives)

• General disorders and administration site conditions

Uncommon: asthenia

• Investigations

Common: weight increased

Check with your doctor or pharmacist for further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and disposal

-Storage

Store in a dry place below 30°C. Do not use beyond the expiry date printed on the packaging components. Please refer to outer carton for storage condition.

-Disposal

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

Keep out of reach of children.

8. Product description

-What it looks like

Ceretam 800mg Film-Coated Tablet

: It is a white to off-white, oblong shaped, film-coated tablet with CC logo and embossed line on both sides of the tablet.

Ceretam Oral Solution 20%w/v:

It is a clear solution with strawberry and banana flavours. Preservatives methylparaben 0.135%w/v and propylparaben 0.015%w/v.

-Ingredients

Active ingredient: Piracetam

Excipients for Ceretam 800mg Film-coated Tablet: macrogol 6000, colloidal silica, croscarmellose sodium, magnesium stearate, hydroxypropylmethylcellulose, titanium dioxide.

Excipients for Ceretam Oral solution 20%w/v: methylparaben, propylparaben, glycerine, strawberry flavour, banana flavour, sodium acetate,

sodium saccharin, acetic acid and purified water.

-MAL Number

Ceretam 800mg Film-Coated Tablet
 (MAL07081616AZ)

Ceretam Oral Solution 20%w/v
 (MAL07081598AZ)

9. Manufacturer & product registration holder

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10. Date of revision

16 Apr 2020

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