

CIZINATE®

Cinnarizine and dimenhydrinate tablets

Consumer Medicine Information

Please read this leaflet carefully before you start CIZINATE.

What is in this leaflet

This leaflet answers some common questions about CIZINATE tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CIZINATE against the benefits this medicine is expected to have for you.

Keep this leaflet with the medicine. You may need to read it again.

What CIZINATE is used for

CIZINATE contains two active ingredients. One is cinnarizine and one is dimenhydrinate. The two substances belong to different groups of medicines. Cinnarizine is part of a group called calcium antagonists and also has anti-dopamine and anti-histamine effects. Dimenhydrinate belongs to a group called antihistamines.

Both substances work by reducing symptoms of vertigo (a feeling of dizziness or 'spinning') and nausea (feeling sick). When these two substances are used together they are more effective than when each one is used on its own.

CIZINATE is used for short-term symptomatic treatment of vertigo of various causes, in adults who have not responded to alternative

treatments. Vertigo can have a number of different causes.

Your doctor may have prescribed CIZINATE for another reason. Ask your doctor if you have any questions about why CIZINATE has been prescribed for you.

There is no evidence that CIZINATE is addictive.

This medicine is available only with a doctor's prescription.

Before you take CIZINATE

When you must not take it

Do not take this medicine if you have an allergy to:

- Cinnarizine and/or dimenhydrinate the active ingredients, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as diphenhydramine or other antihistamines such as chlorpheniramine

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 take CIZINATE if you:

- have severe kidney problems (renal impairment)
- have severe liver problems (hepatic impairment)

- suffer from angle-closure glaucoma (a specific type of eye disease)
- have convulsions, fits or seizures (epilepsy)
- have increased pressure in the brain
- suffer from alcohol abuse
- have prostate problems which cause difficulty in urinating

Do not give CIZINATE to children under 18 years of age.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take CIZINATE after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering, or if the tablets do not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking CIZINATE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- low or high blood pressure
- severe heart disease
- raised pressure in the eye
- obstruction in the bowels
- an enlarged prostate
- an overactive thyroid
- kidney or liver problems
- movement disorders such as disease of the brain affecting movement (Parkinson's disease) or tremor

- depression

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking CIZINATE.

Taking other medicines

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

CIZINATE may interact with other medicines that you are taking.

CIZINATE may increase the effects of the following medicines:

- tricyclic antidepressants (used to treat depression and anxiety)
- atropine (a medicine that relaxes muscles and is often used to examine your eye)
- ephedrine (can be used to treat cough or blocked nose)
- procarbazine (a medicine used to treat some kinds of cancer)
- medicines taken to lower blood pressure

Amino glycosides (a type of antibiotic) can damage the inner ear. If you take CIZINATE you may not notice that this damage is happening.

You should not take CIZINATE with drugs that are used to correct problems with your heart beat (anti-arrhythmics).

CIZINATE can make you tired or sleepy when taken with the medicines listed below:

- barbiturates (medicines that are often taken to calm you down)
- narcotic analgesics (strong painkillers such as morphine and codeine)
- any antihistamine medications
- tranquillisers (a type of medicine used to treat depression and anxiety)

- monoamine oxidase inhibitors (used to treat depression and anxiety)

You should avoid alcoholic drinks while taking CIZINATE.

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

CIZINATE may change the way your skin reacts to allergy tests.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking CIZINATE.

How to take CIZINATE

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

The standard dose for this medicine is one tablet three times a day.

Your doctor may have prescribed a different dose.

Do not take more than the dose your doctor has prescribed for you.

CIZINATE is not intended to be used longer than for 4 weeks at a time.

How to take it

CIZINATE tablets should be swallowed without chewing and with a glass of liquid.

When to take it

Take CIZINATE immediately after a meal, at about the same time each day.

If you take CIZINATE on an empty stomach, it may cause stomach upsets.

Taking your tablets at the same time each day will have the best effect. It

will also help you remember when to take the tablets.

How long to take it

Usually you will take CIZINATE for up to 4 weeks. Your doctor will tell you if you need to take CIZINATE for any longer.

Continue taking your medicine for as long as your doctor tells you.

If you forget to take your tablets

If you forget to take a tablet of CIZINATE just miss out that tablet. Take the next tablet of CIZINATE the next time when you would usually take it.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately contact your doctor or pharmacist or the Poisons Information Centre (In Australia telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much CIZINATE. Do this even if there are no signs of discomfort or poisoning.

If you take too much CIZINATE you may become very tired, dizzy and shaky. Your pupils might dilate and you may not be able to urinate. Your mouth may feel dry, your face flush, you may have a faster heart rate, fever, sweat and have a headache.

If you have taken a massive amount of CIZINATE you could have fits, hallucinations, high blood pressure, feel shaky, get excited, and find it difficult to breathe. Coma could occur.

While you are taking CIZINATE

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking CIZINATE.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking CIZINATE.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking CIZINATE.

If you become pregnant while taking CIZINATE, tell your doctor immediately.

Things you must not do

Do not give CIZINATE to anyone else, even if they have the same condition as you.

Do not take CIZINATE to treat any other complaints unless your doctor tells you to.

Do not stop taking CIZINATE, or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how CIZINATE affects you.

CIZINATE may cause drowsiness in some people. If you have these symptoms, do not drive, 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 taking CIZINATE.

All medicines can have side effects. Sometimes they are serious, 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 the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list.

You may not experience any of them.

If you get any side effects, do not stop taking CIZINATE without first talking to your doctor.

Common side effects (affect up to 1 in 10 people):

- drowsiness
- dry mouth
- headache
- stomach pain

If CIZINATE causes stomach pain this may be reduced if CIZINATE is taken with food.

These are usually mild and disappear within a few days even if you keep taking CIZINATE.

Uncommon side effects (affect up to 1 in 100 people):

- sweating
- reddening of the skin
- indigestion
- nausea (feeling sick)
- diarrhea
- nervousness
- cramps
- forgetfulness
- tinnitus (ringing in the ear)
- paraesthesia (tingling of the hands or feet)
- tremor (shaking)

Rare side effects (affect up to 1 in 1,000 people):

- impaired vision
- allergic reactions (e.g. skin reactions)
- light sensitivity
- difficulty in urinating

Very rare side effects (affect fewer than 1 in 10,000 people):

- weakness
- bruising
- infections more likely

If you suffer from infections with fever and serious deterioration of your general health, see your doctor and tell him about your medicine.

Other possible reactions which may occur with this type of medicine include:

- weight gain
- constipation
- tightness of the chest
- jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- increased pressure inside the eye
- unusual excitement and restlessness
- severe skin reactions

If you notice any of the following, stop taking CIZINATE and tell your doctor immediately:

- skin reactions
- difficulty breathing
- severe eye pain

These may be serious side effects. You may need medical attention. Serious side effects are very rare.

If you notice any of the following, stop taking CIZINATE and tell your doctor immediately:

- convulsions or fitting
- uncontrollable movements of the body or face
- trembling and shaking of the hands and fingers
- twisting movement of the body
- muscle stiffness with difficulty walking
- stiffness of the arms and legs
- severe feeling of restlessness and desire to keep moving

These side effects affecting the nervous system are known as “extrapyramidal” effects and may be serious. You may need immediate medical attention.

They have been reported more frequently in older people, women and people taking high doses for long periods of time. In rare cases these effects are irreversible.

Other side effects not listed above may occur in some patients. Tell

your doctor or pharmacist if you notice anything that is making you feel unwell.

After using CIZINATE

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store CIZINATE or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep CIZINATE tablets where children cannot reach them.

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 taking CIZINATE, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What the tablets look like

CIZINATE tablets are white to almost white, round, biconvex uncoated tablets.

They are available in packs of 20, 30, 50 and 100 tablets.

Ingredients

Each CIZINATE tablet contains the following active ingredients:

- 20 mg cinnarizine
- 40 mg dimenhydrinate

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- maize starch
- hypromellose
- colloidal anhydrous silica
- purified talc
- magnesium stearate

Supplier

CIZINATE is supplied in Australia by:

Southern Cross Pharma Pty Ltd
Suite 5/118 Church Street
Hawthorn, VIC, 3122

ABN 47 094 447 677

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