

COGENTIN[®]

2mg Tablet & 1mg vial for Injection
Benzotropine mesylate

Consumer Medicine Information

What is in this leaflet

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using COGENTIN against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What COGENTIN is used for

COGENTIN is used to treat some of the symptoms of parkinsonism.

The symptoms of parkinsonism include slow and unsteady movement, muscle stiffness and shaking (tremors). If untreated, parkinsonism can cause difficulty in performing normal daily activities.

Symptoms of parkinsonism can be caused by certain diseases of the brain affecting movement, such as Parkinson's disease. They can also be caused by some medicines that are used to treat certain mental conditions.

COGENTIN is most helpful in improving muscle stiffness and shaking.

How does COGENTIN work?

It is believed that the symptoms of parkinsonism are caused by a lack of dopamine, a naturally occurring chemical produced by certain brain cells. When not enough dopamine is present, acetylcholine which is another naturally occurring chemical produced by brain cells, can interfere with the regions of the brain that control muscle movement.

COGENTIN blocks the effects of acetylcholine. In many patients, this reduces the symptoms of shaking and muscle stiffness.

COGENTIN belongs to a group of medicines called anticholinergics. It comes as tablets and as an injection.

Ask your doctor if you have any questions about why COGENTIN has been prescribed for you.

COGENTIN is not addictive.

Before you use COGENTIN

When you must not use it

Do not use COGENTIN if:

- **you have an allergy to COGENTIN or any of the ingredients listed at the end of this leaflet**

If you are not sure whether you should start using COGENTIN, talk to your doctor.

Do not give COGENTIN to a child under three years old.

Also, it should be used with caution in older children.

Before you start to use it

Your doctor must know about all the following before you start to use COGENTIN.

- 1. if you are pregnant, intend to become pregnant, are breast-feeding or plan to breast-feed**

Your doctor will discuss the possible risks and benefits of using COGENTIN during pregnancy or while breast-feeding.

- 2. if you have any medical conditions, especially the following:**

- heart problems, such as fast heart beat
- enlarged prostate
- mental illness
- glaucoma
- uncontrolled movements of hands, mouth or tongue

- 3. if you consume large quantities of alcohol**

- 4. if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you use any COGENTIN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and COGENTIN may interfere with each other. These include:-

- some medicines used to treat mental illness or psychotic disorders
- a group of medicines called tricyclic antidepressants used to treat depression
- other anticholinergic medicines, such as procyclidine, orphenadrine

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If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Taking COGENTIN with these medicines may cause fever, heat intolerance, and stomach or bowel problems. Therefore, you may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

COGENTIN may be taken with certain other medicines, such as levodopa and carbidopa, for the treatment of the symptoms of parkinsonism.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while using COGENTIN.

How to use COGENTIN

How much to use

Use COGENTIN only when prescribed by your doctor.

Your doctor will tell you how many tablets you need to take each day or will decide how much injection to give you. This depends on your symptoms, age, weight and whether you are taking other medicines. The dose varies considerably from patient to patient.

The usual dose of COGENTIN is 1 to 2 mg per day, with a range of 0.5 to 6 mg per day. The dose may be taken as tablets or given as the injection.

Older people are usually more sensitive to medicines like COGENTIN and therefore cannot tolerate large doses. Your doctor will take your age into consideration when prescribing the tablets.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

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

If you are taking the tablets, swallow them with a glass of water.

How long to use it

COGENTIN helps control some of your symptoms of parkinsonism, but does not cure them. Therefore COGENTIN must be used for as long as your doctor prescribes.

If you forget to take the tablets

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too many tablets (overdose)

Immediately telephone your doctor or National Poisons Information Centre (telephone 03-474-7000) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much COGENTIN. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers of these places handy.

If you take too many tablets, you may experience the effects listed under the adverse effects section. You may also have other effects, including decreased or increased reaction time, dizziness, poor co-ordination, muscle weakness, inability to perspire, hot and dry

flushed skin, headache, breathing difficulties, fits and unconsciousness.

Also, symptoms of existing mental illness may worsen after taking an overdose.

While you are using COGENTIN

Things you must do

If you experience problems with sweating while using COGENTIN tell your doctor immediately.

Under certain conditions COGENTIN may make you perspire or sweat less, which may cause heat stroke. This may happen during hot weather, especially if you:

- drink large quantities of alcohol
- are being treated with other anticholinergic medicines for a chronic illness
- have a nervous (neurological) disorder
- will be working in a hot environment
- have an existing problem with sweating

Your doctor may need to reduce your dose of COGENTIN.

Try to avoid becoming overheated during exercise or hot weather while you are using this medicine.

COGENTIN may make you sweat less, causing your body temperature to increase. If you overheat during exercise or hot weather you may get heat stroke.

If you become pregnant while using COGENTIN tell your doctor.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using COGENTIN.

Things you must not do

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

Things to be careful of

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

COGENTIN may cause some people to have blurred vision or to become less alert than normal. Make sure you know how you react to COGENTIN before you drive a car, operate machinery or do anything else that could be dangerous if you are not alert or able to see well.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COGENTIN.

COGENTIN helps most people with certain symptoms of parkinsonism, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Tell your doctor if you notice any of the following and they worry you:

- constipation
- dry mouth, or difficulty swallowing or speaking due to dry mouth
- feeling sick, also called nausea, vomiting
- loss of appetite, weight loss
- blurred vision, dilated pupils
- increased heart rate

These are possible adverse effects of COGENTIN. For the most part these have been mild.

Tell your doctor immediately if you notice any of the following:

- difficult or painful urination
- an allergic reaction, for example skin rash
- mood or mental changes such as depression, nervousness, unusual laziness or sleepiness,

confusion, disorientation, memory loss

- numb fingers
- seeing things that are not there, also called visual hallucinations
- worsening symptoms of existing mental illness

These are serious adverse effects. You may need urgent medical attention. Serious adverse effects are generally rare.

Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- heat stroke, fever, raised body temperature
- it becomes impossible to empty your bladder (urinary retention)

These are serious adverse effects that need urgent medical attention. These adverse effects are generally rare.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using COGENTIN

Storage

Tablets:

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

If you take the tablets out of the bottle they may not keep well.

Keep it in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the

ground is a good place to store medicines.

Injection:

COGENTIN will be stored by the doctor.

The injection is kept in a cool dry place where the temperature stays below 30°C. The ampoules are kept in their package to protect them from light. The ampoules must not be stored in the freezer.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Tablets:

- COGENTIN 2 mg - white, round tablets with 'MSD60' marked on one side and scored on the other side marked COGENTIN.

Bottles dispensed to the pharmacy contain 100 tablets. These may be repacked by the pharmacist into smaller containers for patients prescriptions.

Injection:

COGENTIN comes as a clear, colourless solution in a glass ampoule. The amount of solution in each ampoule is 2 mL.

Ingredients

Tablets:

Active ingredient:

- COGENTIN 2 mg - 2 mg benzotropine mesylate per tablet

Inactive ingredients:

- calcium hydrogen phosphate
- lactose
- cellulose
- maize starch
- magnesium stearate

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COGENTIN does not contain gluten, sucrose, tartrazine or any other azo dyes.

Injection:

Active ingredient:

- benztropine mesylate 1 mg per mL

Inactive ingredients:

- sodium chloride
- water for injection

Supplier

COGENTIN is supplied in New Zealand by:-

Merck Sharp & Dohme (New Zealand) Limited
P O Box 23244
Hunters Corner
AUCKLAND

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