

COGENTIN[®]

Benztropine mesylate

Consumer Medicine Information (CMI)

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 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 COGENTIN

Do not use COGENTIN if:

- you have an allergy to COGENTIN or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

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 COGENTIN

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 benzhexol, biperiden, procyclidine, orphenadrine

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 decide how much to inject. 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 will be given as an 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 giving the injection.

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, ask your doctor or pharmacist for help.

How long to use COGENTIN

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 it.

If you have too much COGENTIN (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) 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 have too much COGENTIN, you may experience the effects listed under the side effects section. You may also have other effects, including decreased or increased reaction time, dizziness, poor coordination, 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

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.

Side 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 side effects in a few people. 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.

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 side 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 side effects. You may need urgent medical attention. Serious side 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 side effects that need urgent medical attention. These side effects are generally rare.

Other side 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 side effects. You may not experience any of them.

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.

Product description

What COGENTIN looks like

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

A box contains 5 ampoules.

Ingredients

Active ingredient:

- benzotropine mesylate 1 mg per mL

Inactive ingredients:

- Sodium Chloride
- Water for injection

Supplier

COGENTIN is supplied by:

Australia

A. Menarini Australia Pty Ltd.,
Level 8, 67 Albert Avenue
Chatswood NSW 2067 Australia
☎: 1800 642 646

New Zealand

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4 Whetu Place,
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After using COGENTIN

Storage

COGENTIN Injection will be stored by the doctor.