

Benztrop[™]

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Benztrop?

Benztrop contains the active ingredient benzatropine mesilate. Benztrop is used to treat all forms of parkinsonism and the side effects of some medicines that are used to treat mental conditions.

For more information, see Section 1. Why am I using Benztrop? in the full CMI.

2. What should I know before I use Benztrop?

Do not use if you have ever had an allergic reaction to Benztrop or any of the ingredients listed at the end of the CMI.

Do not use this medicine if you have narrow-angle glaucoma and a rare condition called tardive dyskinesia.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Benztrop? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Benztrop and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Benztrop?

- Always take Benztrop exactly as your doctor has told you.
- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section 4. How do I use Benztrop? in the full CMI.

5. What should I know while using Benztrop?

Things you should do	 Remind any doctor, dentist, pharmacist or nurse you visit that you are using Benztrop. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Benztrop.
Things you should not do	 Do not take Benztrop to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	Be careful driving or operating machinery until you know how Benztrop affects you.
Drinking alcohol	Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, you may become more drowsy and sleepy.
Looking after your medicine	 Store below 25°C. Do not store Benztrop or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Keep it where children cannot reach it.

For more information, see Section 5. What should I know while using Benztrop? in the full CMI.

6. Are there any side effects?

Benztrop may cause constipation, dry mouth causing difficulty swallowing, nausea and/or vomiting, loss of appetite, weight loss, blurred vision, dilated pupils, difficulty or pain passing urine, skin rash and swelling of the face, lips, tongue or throat.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.



Benztrop[™]

Active ingredient(s): benzatropine mesilate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Benztrop. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Benztrop.

Where to find information in this leaflet:

- 1. Why am I using Benztrop?
- 2. What should I know before I use Benztrop?
- 3. What if I am taking other medicines?
- 4. How do I use Benztrop?
- 5. What should I know while using Benztrop?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Benztrop?

Benztrop contains the active ingredient benzatropine mesilate. Benztrop belong to a group of medicines called anticholinergic agents.

Benztrop is used to treat:

- all forms of parkinsonism.
- · the side effects of certain drugs.

Symptoms of parkinsonism can be caused by certain diseases of the brain affecting movement. They can also be caused by some medicines that are used to treat some mental illnesses. This medicine works by improving shaking and muscle stiffness.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I use Benztrop?

Warnings

Do not use Benztrop if:

- you are allergic to benzatropine mesilate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have narrow-angle glaucoma.
- you have a rare condition called tardive dyskinesia that causes uncontrollable twitching or jerking movements of the arms and legs.

Check with your doctor if you have or have had:

- · heart problems such as fast heartbeat
- prostate problems
- mental illness
- any long term illness
- dehydration
- · difficulty sweating
- glaucoma
- alcoholism
- · difficulty with bowel movements
- any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in Children

Do not give this medicine to a child under the age of 3 years.

3. What if I am taking other medicines?

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

Some medicines may interfere with Benztrop and affect how it works.

These include:

- some medicines used to treat mental illness or psychotic disorders
- a group of medicines called tricyclic antidepressants which are used to treat depression
- other anticholinergic medicines such as benzhexol, biperiden, procyclidine, orphenadrine, levodopa
- alcohol
- medicines to calm and help you sleep such as sedatives, anxiolytics and some pain killers
- metoclopramide medicines used to prevent nausea
- cisapride, a medicine used to treat reflux



- ketoconazole, a medicine used to treat fungal infections
- medicines used to treat glaucoma and oedema, buildup of fluid in the body
- some medicines used to treat Alzheimer's disease and myasthenia gravis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Benztrop.

4. How do I use Benztrop?

How much to take

- The dose can range from 0.5 mg to 6 mg but is usually 1 to 2 mg.
- Follow the instructions provided and use Benztrop until your doctor tells you to stop.

When to take Benztrop

 Benztrop should be used at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take Benztrop

Swallow the tablets whole with a full glass of water.

If you forget to use Benztrop

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 medicine as you would normally.

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

If you use too much Benztrop

If you think that you have used too much Benztrop, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre in Australia (by calling 13 11 26), or the New Zealand National Poisons Centre (by calling 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Benztrop?

Things you should do

Tell your doctor if you experience signs and symptoms such as:

- confusion, seeing or hearing things that are not there
- nervousness, shock, listlessness
- dizziness, headache
- poor coordination, unsteadiness when walking
- muscle weakness, numbness in fingers
- · dry mouth, difficulty swallowing
- dilated pupils, blurred vision, pressure in the eye
- fast or irregular heartbeats
- nausea, vomiting
- pain when urinating
- · fever, hot and dry flushed skin
- skin rash
- constipation
- breathing difficulties
- convulsions, fits or seizures
- difficulty sweating
- loss of consciousness.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Benztrop.

Tell any other doctors, dentists, pharmacists or nurses who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

• become pregnant while taking this medicine.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Benztrop.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not take Benztrop to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Benztrop affects you.

Benztrop may cause dizziness in some people.

This medicine may cause blurred vision or cause you to be less alert than normal. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.



Alcohol may make you become more drowsy and sleepy. Be careful when drinking alcohol while you are taking this medicine.

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them
- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye related: • Blurred vision, dilated pupils Gastrointestinal related: • constipation • nausea and/or vomiting • loss of appetite, weight lost	Speak to your doctor if you have any of these less serious side effects and they worry you.
Mouth related: • dry mouth causing difficulty swallowing	

Serious side effects

Serious side effects	What to do
Cardiovascular: • increased heart rate	Call your doctor straight away, or go straight
Gastrointestinal related: • severe pain in the stomach with bloating and gut cramps Infection: • raised body temperature or fever with lack of sweating	to the Emergency Department at your nearest hospital if you notice any of these serious
 swelling of the face, lips, tongue or throat Musculoskeletal: numb fingers 	side effects.
Nervous system: changes in mood or mental ability such as depression, nervousness, tiredness or sleepiness, confusion disorientation or memory loss hallucinations worsening symptoms of an existing mental illness Skin related: skin rash Urinary tract related: unable to pass urine difficulty or pain passing urine	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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



What Benztrop contains

Active ingredient	benzatropine mesilate
(main ingredient)	
Other ingredients (inactive ingredients)	pregelatinised maize starch lactose monohydrate microcrystalline cellulose magnesium stearate

Benztrop tablets contains sugars (as lactose monohydrate).

This medicine does not contain sucrose, gluten, tartrazine, alcohol, dyes or preservatives.

Do not take this medicine if you are allergic to any of these ingredients.

What Benztrop looks like

Benztrop 2 mg tablets are round, flat-faced white tablets, quarter-scored on one side and debossed with "PMS 2" on the other side (AUST R 83130).

Who distributes Benztrop

Benztrop is supplied in Australia by:

Phebra Pty Ltd

19 Orion Road, Lane Cove West,

NSW 2066, Australia.

Telephone: 1800 720 020

Benztrop is distributed in New Zealand by:

AFT Pharmaceuticals Ltd

PO Box 33-203 Auckland.

Telephone: +64 9 4880232

This leaflet was prepared in June 2021.

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