

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARTANE. It does not contain all of 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 taking ARTANE 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 ARTANE is used for

ARTANE is used along with other medicines to help treat Parkinson's disease.

Parkinson's disease is a brain disorder, which affects movement. The symptoms of Parkinson's disease include trembling, rigid posture, slow movements and a shuffling unbalanced walk.

ARTANE is also used after illnesses, which have after-effects like Parkinson's disease.

ARTANE can also be used to help prevent tremor or shaking, which have been caused by tranquillisers such as reserpine and phenothiazines.

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

Your doctor, however, may have prescribed ARTANE for another purpose.

ARTANE belongs to a group of medicines known as antidyskinetics. It works by relaxing muscle tissue and by acting on the nerves, which control the working of muscles.

ARTANE is not habit forming.

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

Before you take ARTANE

When you must not take it

Do not take ARTANE if you have an allergy to:

- any medicine containing benzhexol hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Some symptoms of an allergic reaction include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not take ARTANE if you have narrow angle glaucoma, a condition often associated with an increase in pressure of the eye.

Do not take ARTANE if the packaging is torn or shows signs of tampering.

Do not take ARTANE after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of ARTANE in children have not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if:

1. you have any allergies to any other medicines, foods, preservatives or dyes.

2. you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking ARTANE during pregnancy.

3. you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of taking ARTANE when breastfeeding.

4. you have or have had any other medical conditions including:

- liver, kidney or heart disease
- high blood pressure
- glaucoma (high pressure in the eye)
- problems with your stomach or bowel
- difficulty urinating
- prostate problems
- an inability to sweat normally

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

Taking other medicines

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

Some medicines may interfere with ARTANE. These include:

- medicines used to treat depression (eg. barbiturates, opiates,

- monoamine oxidase inhibitors, tricyclic antidepressants)
- other medicines used to treat Parkinson's disease, movement disorders or muscle spasms (eg. levodopa, anticholinergics)
- medicines used to treat certain nerve disorders
- medicines used to control epilepsy
- medicines used to relieve nausea (eg. metoclopramide)
- medicines used to treat glaucoma (eg. acetazolamide)
- magnesium hydroxide (eg. antacids)

These medicines may be affected by ARTANE or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

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

How to take ARTANE

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 on the bottle, ask your doctor or pharmacist.

How much to take

The dose of ARTANE may be different for each person. Your doctor will decide the right dose for you.

If you are over 60, your starting dose will be low and then increased gradually.

The starting dose is usually 1mg on the first day. The dose may then be increased by 2 mg at a time every three to five days until a total dose of 6 to 10 mg is taken daily.

Some people may need to take a daily dose of 12 to 15 mg.

If you are taking ARTANE for tremor or shaking caused by other medicines,

the usual daily dose is between 5 and 15 mg.

How to take it

Swallow ARTANE with a glass of water.

When to take it

ARTANE may be taken with or without food. ARTANE makes some people feel very thirsty. How you react to ARTANE will determine if it is better for you to take ARTANE before or after meals.

If you salivate a lot, take ARTANE after meals.

If you find ARTANE makes your mouth very dry, take it before meals unless it makes you feel sick.

If you take ARTANE after meals, mint candies, chewing gum or water can help lessen the thirst.

Take ARTANE three times a day at mealtimes, if you are on a lower dose.

Take ARTANE four times daily, with three doses at mealtimes and the fourth dose at bedtime, if you are on a higher dose.

How long to take it

Continue taking ARTANE as long as your doctor recommends it.

You may need to take ARTANE indefinitely.

If you forget to take it

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 it as you would normally

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

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

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

If you take too much (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 ARTANE. Do this even if there are no signs of discomfort or poisoning. Also report any other medicine or alcohol, which has been taken. You may need urgent medical attention. Keep telephone numbers for these places handy.

While you are using ARTANE

Things you must do

Use ARTANE exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking ARTANE.

Tell your doctor immediately if you develop an allergy to ARTANE.

ARTANE can cause allergies unexpectedly, even if you have been taking it for a long time.

If you become pregnant while you are taking ARTANE, tell your doctor.

Tell your doctor if you feel ARTANE is not helping your condition.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking ARTANE. Your doctor will also want to check the pressure in your eyes regularly as ARTANE may affect your vision.

Always discuss with your doctor any problems or difficulties during or after taking ARTANE.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough ARTANE to last weekends and holidays.

Things you must not do

Do not drive or operate machinery until you know how ARTANE affects you.

ARTANE may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to ARTANE before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Do not stop taking ARTANE or change the dose, without first checking with your doctor.

Especially if you are over 60 years, the dose of ARTANE must be strictly adhered to, as you are more likely to become sensitive to its effects.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give ARTANE to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion or dizziness, which may increase the risk of a fall.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness and dizziness may be worse. Alcohol may also decrease the affect of ARTANE.

Side effects

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

ARTANE helps most people with Parkinson's disease, but it may have unwanted side effects in some people.

All medicines may 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:

- dryness of the mouth
- blurred vision
- dizziness
- feeling sick or nausea
- nervousness

These are the more common side effects of ARTANE. These side effects usually go away with time. If they persist you may need to have your dose changed.

The following side effects are rare:

- swelling of your salivary glands
- rash
- bowel problems
- confusion
- agitation
- delusions, or disturbed behaviour
- seeing, feeling or hearing things that are not there

Other side effects that have been reported in medicines that work the same way as ARTANE include:

- constipation
- drowsiness
- difficulty passing urine
- fast heart beat
- enlarged pupils
- increased pressure in the eye
- weakness
- vomiting
- headache

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell

when you are taking, or soon after you have finished taking, ARTANE.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After using ARTANE

Storage

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

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

Keep ARTANE in a cool dry place where the temperature stays below 25°C. Do not store it, or any other medicines, in a 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.

Disposal

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

Product description

What it looks like

ARTANE tablets come in two strengths.

ARTANE 2 mg tablets are white and scored.

ARTANE 5 mg tablets are white and scored.

Both ARTANE 2 mg and 5 mg tablets come in bottles of 200 tablets.

Ingredients

The active ingredient in ARTANE is benzhexol hydrochloride.

Each ARTANE 2 mg tablet contains 2 mg benzhexol hydrochloride.

Each ARTANE 5 mg tablet contains 5 mg benzhexol hydrochloride.

ARTANE also contains the following inactive ingredients:

- calcium hydrogen phosphate
- maize starch
- pregelatinised maize starch
- magnesium stearate

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

Supplier

ARTANE tablets are supplied by:
Sigma Pharmaceuticals (Australia) Pty
Ltd
(ACN 004 118 594)
96 Merrindale Drive
Croydon Victoria 3136
AUSTRALIA

Australian Registration Numbers:

- ARTANE 2mg Tablets - AUST R
15125
- ARTANE 5mg Tablets - AUST R
15126

This leaflet was prepared on the 8th
April 2003 and last revised on the 15th
April 2005.

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