

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Artige tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child taking this medicine against the benefits they expect it will provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Artige is used for

Artige tablets contain the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant.

Artige tablets have two uses. They are used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD); and
- narcolepsy, a sleep-attack disorder.

Your doctor may have prescribed it for another purpose.

This medicine should not be used to prevent or treat normal fatigue.

ADHD

About 3% of children suffer from ADHD. It makes them unable to sit still or concentrate on tasks for any length of time. They may have trouble learning and doing school work. They frequently become difficult to manage, both in school and at home.

Artige is thought to work by regulating specific chemicals in the brain that affect behaviour. It helps to focus attention, shut out distraction and allows impulsive people to think before they act. If successful, it will enhance an inattentive person's natural ability.

This medicine is part of a treatment program that usually includes psychological, educational and social therapy.

Narcolepsy

People with narcolepsy have recurring attacks of irresistible day-time sleepiness in spite of having enough sleep at night. Narcolepsy can be diagnosed by a doctor by recording wake-sleep patterns.

Narcolepsy is not a normal fatigue state.

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

Artige, like all medicines containing central nervous system stimulants, will be given to you/your child only under close medical supervision and after diagnosis.

This medicine is only available with a doctor's prescription and your doctor has special permission to prescribe it.

There is not enough information to recommend its use in children under 6 years old.

Artige can be abused or lead to dependence.

Keep Artige in a safe place to prevent misuse and abuse.

Before you take Artige

When you must not take it

Do not take Artige if you/ your child are allergic (hypersensitive) to methylphenidate (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

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 Artige if you/ your child have any of the following medical conditions:

- periods of severe anxiety, tension or agitation

- Tourette's syndrome (a condition with uncontrolled speech and body movements or tics) or you have a family history of this disorder
- glaucoma (increased pressure in the eye)
- an overactive thyroid or other thyroid problems
- heart problems such as heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or if you were born with a heart problem
- very high blood pressure (hypertension) or narrowing of the blood vessels (arterial occlusive disease, which can cause pain in the arms and legs)
- severe depression or other mental illness
- pheochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney)

If you are not sure whether any of the above medical conditions apply to you/ your child, check with your doctor.

Do not take Artige if you/ your child are taking a medicine called a monoamine oxidase inhibitor (MAOI) or have been taking it within the past 14 days.

Taking Artige together with MAOI medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Ask your doctor or pharmacist if you are not sure if you/ your child have been taking one of these medicines.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if you/ your child are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you or your child are prone to allergies.

Tell your doctor if you/ your child have intolerance to lactose or gluten.

This medicine contains lactose and wheat starch.

Tell your doctor if you/ your child have any of the following medical conditions or behaviours:

- any heart defects (e.g. structural cardiac abnormality)
- a family history of sudden death or irregular heart beat
- hardening of the arteries
- any other current or previous heart problems
- any disorders of the blood vessels in the brain, e.g. weakening of the blood vessel (aneurysm), stroke, or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illness
- epilepsy (seizures, convulsions, or fits)
- high blood pressure
- history of alcohol or drug abuse or dependence
- tics (muscle twitching which is usually in the face or shoulders) or if your brothers or sisters have tics
- acute mental disorders that cause abnormal thinking and perceptions (psychosis) or feeling unusually excited, over-active and un-inhibited (acute mania) - your doctor will have told you if you have this
- psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- aggressive behaviour
- suicidal thoughts or behaviour

- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').
- have or develop eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness).

Your doctor may want to take special precautions if you/your child have any of the above conditions.

Tell your doctor if you are pregnant or breast-feeding.

Ask your doctor about the risks and benefits of taking Artige in this case.

Artige is not to be used during pregnancy unless specifically prescribed by your doctor.

This medicine may affect your developing baby if you take it while you are pregnant.

Do not breast-feed during treatment with Artige.

The active ingredient in Artige can pass into the breast milk.

Taking other medicines

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

Some medicines and Artige may interfere with each other. These include:

- medicines that increase blood pressure
- alpha 2 agonists like clonidine (used to treat high blood pressure)
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- some anticonvulsants (medicines used to treat epilepsy or fits)
- medicines used to treat depression, such as tricyclic antidepressants and monoamine

oxidase inhibitors (MAO inhibitors)

- phenylbutazone (used to treat pain or fever)
- guanethidine
- anaesthetics
- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis)
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine).

You or your child may need to take different amounts of your medicines or you or your child may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you or your child start taking this medicine.

How to take Artige

Your doctor will decide on the most suitable dosage according to the individual patient's medical need and response.

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

They may differ from the information contained in this leaflet.

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

How much to take

Artige is available in tablets containing 10 mg of methylphenidate hydrochloride as the active ingredient.

For children aged 6 or over, the usual starting dose is 5 mg (half a tablet) once or twice each day. If necessary, the dose can be increased

by 5 or 10 mg each week up to a maximum of 60 mg (6 tablets) each day.

For adults, the usual dose is 20 to 30 mg (2-3 tablets) each day but some people may need more or less than that.

Do not exceed the recommended dose.

The maximum dose is 60 mg (6 tablets) each day.

How to take it

You can take Artige tablets with or without food. Take the tablet(s) with a full glass of water.

If they upset you or your child's stomach, you or your child can take them with food, but always take them in the same way (e.g. always with food or always without food).

That way the effect will always be the same.

Take the tablets in 2 or 3 doses over the day unless your doctor tells you otherwise. If you find that you or your child have trouble sleeping, talk to your doctor about the best time to take the last dose of the day.

Each dose is usually taken 1 or 2 hours before the greatest effect is needed. For example, a child may take a dose at 7:00 a.m. so that improved concentration begins when school starts.

How long to take it

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

This medicine helps to control your or your child's symptoms but does not cure your condition. Your doctor will check your/ your child's progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Treatment for ADHD varies in length from patient to patient. During treatment for ADHD, your doctor may stop Artige every so often (e.g. over weekends or school

holidays) to see whether it is still needed. Breaks from treatment also help to prevent a slow-down in growth that sometimes happens when children take this medicine for a long time.

If you forget to take it

If you/ your child forget to take a dose of Artige, take the dose as soon as you remember. Then make sure to wait the same amount of time as usual before you/ your child take the next dose. For example, if there are usually 4 hours between doses, wait 4 hours before taking the next dose and so on for the rest of that day. On the next day go back to your usual times.

Do not take a double dose to make up for the one that you/ your child missed.

Your chance of an unwanted side effect may be increased if you do.

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 the Poisons Information Centre (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 Artige. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

Some of the symptoms of an overdose may include:

- vomiting
- agitation
- headache
- tremors
- muscle twitching
- irregular heart beat
- flushing
- fever
- sweating
- dilated pupils

- breathing problems
- confusion
- seizures.
- muscle spasms, fever, red-brown urine

While you are taking Artige

Things you must do

Take Artige exactly as your doctor has prescribed.

Like all stimulants, this medicine may become habit-forming and can be abused by some people. If you/ your child take it correctly as instructed by your doctor, abuse or dependence should not be a problem, either now or later in life.

Be sure to keep all of your doctor's appointments so that your/ your child's progress can be checked.

Your doctor will want to check your or your child's blood pressure, height, weight and do blood tests from time to time to prevent unwanted side effects from happening.

If your child is not growing or gaining height or weight as expected treatment with Artige may need to be interrupted.

If you become pregnant while taking Artige, tell your doctor.

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

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

Tell any doctor, dentist or pharmacist who treats you or your child that you are taking Artige.

Things you must not do

Do not drink alcohol while you are taking Artige. Remember that

some foods and medicines contain alcohol.

Alcohol can worsen some of the unwanted effects of this medicine, such as dizziness and drowsiness.

Do not stop your treatment without first checking with your doctor.

If you suddenly stop taking this medicine, your condition may reappear or you may get unwanted effects such as depression. To prevent this, your doctor may want to gradually reduce the amount of medicine you take each day before stopping it completely.

You will need medical supervision after having interrupted the treatment.

Do not change the dose without talking to the doctor. If you have the impression that the effect of Artige is too strong or too weak, talk to the doctor.

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

Do not give it to anyone else, even if their condition seems similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Artige until you know how it affects you.

This medicine may cause:

- hallucinations
- dizziness
- drowsiness
- blurred vision
- other central nervous system side effects which can affect concentration in some people.

If you experience any of these symptoms, do not drive, use machines, or do anything else that needs quick reactions or could be dangerous.

Artige may give a false positive result when testing for drug use. This includes testing used in sport.

Some children taking Artige for a long time may have slower than normal growth, but they usually catch up once the treatment is stopped.

In some patients Artige may cause stomach upset, loss of appetite and difficulty sleeping, especially at the start of treatment. Your doctor can usually help to reduce these symptoms by lowering the dose of Artige or changing the times when the tablets are taken.

Tell your doctor if you are going to have an operation.

There is a chance of a sudden rise in blood pressure during the operation if an anaesthetic is used. Your doctor will advise if you/ your child should take Artige on the day of the operation.

If you experience abnormally sustained or frequent and painful erections of the penis on Artige treatment or after treatment discontinuation, you may need urgent medical treatment. This can occur in any age group.

If this occurs, tell your doctor immediately.

If taking Artige with medicines that raise the level of serotonin in the body (serotonergic medicines, e.g. sertraline and venlafaxine used to treat depression) and you experience a combination of the following symptoms: restlessness, tremor, sudden muscle contractions, abnormal high temperature, nausea and vomiting stop treatment with Artige and these medicines and tell your doctor immediately.

Side effects

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

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 these lists of possible side effects. You may not experience any of them. 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:

- excessive emotional distress or excitement
- nervousness
- feeling anxious, agitated
- feeling jittery
- feeling depressed
- feeling aggressive
- unusually active, depressed mood
- uncontrolled speech and body movements (Tourette's syndrome)
- troubled sleep or restlessness, difficulty falling asleep, sleep disturbance, sleepiness
- nausea (feeling sick)
- dry mouth
- vomiting, stomach pain, upset stomach, indigestion, toothache
- loss of appetite, decreased weight
- excessive sweating
- loss of weight and slower growth in children
- sore throat and runny nose
- headache
- cough
- dizziness
- blurred vision or problems focussing your eyes
- muscle cramps
- fever
- hair loss
- abnormal heart rhythm
- palpitations
- involuntary shaking of the body (sign of tremor)
- skin rash, itchy rash and hives
- joint pain
- excessive teeth grinding

- spasm of the jaw muscles that makes it difficult to open the mouth
- stuttering
- bedwetting in children during the night

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

- swelling of the face, lips or tongue (severe allergic reaction)
- sudden high fever, severe convulsions
- severe headache or confusion, weakness or paralysis of limbs or face, difficulty speaking
- fast heartbeat, chest pain
- uncontrollable twitching, jerking
- bruising
- muscle twitching or tics
- a sore throat and fever or chills
- uncontrollable writing movements of the limb, face and/ or trunk
- seeing or feeling things that are not really there (hallucination)
- fits (seizures, convulsions, epilepsy)
- skin blisters or itching
- red blotches on the skin
- prolonged erection, causing discomfort of the penis (sign of priapism)
- thoughts or attempts of killing yourself (suicidal ideation or attempt (including completed suicide)).
- fingers and toes feeling numb, feeling cold, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon, peripheral coldness).
- abnormal decrease in the levels of all type of blood cells. This is associated with anaemia, decreased platelets, and decreased white blood cells. This can lead to fatigue, increased risk of bleeding, and/or increased risk of

infection. This may be serious or life threatening (pancytopenia).

The above side effects may be serious. You may need urgent medical attention.

Other possible side effects with unknown frequency

- Stuttering, swelling of the ears (a symptom of allergic reaction);
- feeling irritated, mood changes, abnormal behaviour or thinking, anger, excessive awareness of surroundings, feeling over-active and un-inhibited (mania), feeling disorientated, changes in sex drive, lack of feeling or emotion, doing things over and over again, being obsessed with one thing, confusion, addiction
- temporary muscle weakness, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischemic neurological deficit), migraine
- double vision, dilated pupils, trouble seeing
- stopped heartbeat, heart attack
- sore throat, shortness of breath
- diarrhoea
- constipation
- swelling of face and throat, excessive sweating, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine;
- muscle pain, muscle twitching;
- Inability to develop or maintain an erection, swelling of the breasts in men
- tiredness
- increased eye pressure (increased intraocular pressure)
- nose bleed

Additional side effects that occurred with other medicines containing the same drug substance of Artige (frequency unknown):

- Blood in the urine
- Chest pain, sudden death of heart origin
- Abnormal sounds from heart.

Tell your doctor if any of these side effects occur or if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

After taking Artige

Storage

- Keep your medicine in the original container until it is time to take a dose.
- Store it in a cool dry place.
- Do not store Artige or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Artige tablets are round white tablets, marked CG on one side and AB with a break-line on the other; packs of 100 tablets.

Ingredients

Artige tablets contain 10 mg of methylphenidate hydrochloride as the active ingredient. They also contain:

- lactose
- calcium phosphate (E341)
- gelatin

- magnesium stearate (E572)
- purified talc (E553b)
- wheat starch

Sponsor

Artige tablets are supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
Macquarie Park NSW 2113
Telephone: 1 800 671 203
Web site: www.novartis.com.au

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