

Aldazine

contains the active ingredient thioridazine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Aldazine.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Aldazine against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Aldazine is used for

Aldazine is used to treat adult schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour.

Aldazine is only used when other antipsychotic medicines do not work or cause severe side effects.

This antipsychotic medicine belongs to a group of medicines called phenothiazines. It helps to correct chemical imbalances in the brain which may cause mental illness.

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

Your doctor may have prescribed Aldazine for another reason.

Aldazine is available only with a doctor's prescription.

There is no evidence that Aldazine is addictive.

Before you take Aldazine

When you must not take it

Do not take Aldazine if you are allergic to:

- * thioridazine
- * other phenothiazine medicines
- * any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing; skin rash, severe sunburn, itching or hives.

Do not take Aldazine with other antipsychotic medicines used to treat mental illnesses.

Do not take Aldazine if you have, or have had, any of the following medical conditions:

- * severe heart disease, especially an irregular heart beat (arrhythmias) or long QT syndrome (an inherited heart condition which may cause dizziness and sudden fainting)
- * certain blood disorders with a reduced number of red or white blood cells or platelets
- * a genetic defect reducing your liver's ability to breakdown certain medicines

- * Pick's disease - a form of dementia that results in memory loss, lack of spontaneity, difficulty in thinking or concentrating, and disturbed speech.

Do not give Aldazine to anyone who is unconscious or in a coma.

Do not give Aldazine to a child.

Do not take Aldazine if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Aldazine if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking Aldazine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Aldazine is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking Aldazine during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Aldazine passes into breast milk. It is recommended that you do not breastfeed while taking Aldazine.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * glaucoma or increased pressure in the eye
- * epilepsy, seizures or fits
- * low levels of magnesium or potassium in your blood
- * difficulty urinating, which may be due to prostate problems
- * chronic constipation
- * diabetes
- * heart problems such as heart failure
- * low blood pressure
- * liver problems
- * kidney problems
- * myasthenia gravis, a condition where there is severe muscle weakness
- * dementia, a disorder where there is loss of memory and other mental abilities
- * Parkinson's disease
- * lactose intolerance, galactosaemia, galactose malabsorption syndrome (Aldazine 10 mg and 100 mg tablets contain lactose).

Tell your doctor if you have had any of the following reactions to a medicine:

- * neuroleptic malignant syndrome (sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and changes in blood pressure, which may lead to coma)
- * tardive dyskinesia (uncontrolled movements of the tongue, face, mouth, cheeks, jaw, arms or legs)
- * an arrhythmia (an irregular heartbeat, sometimes with dizziness and fainting).

Tell your doctor if you will be in a hot environment or do a lot of vigorous exercise.

Aldazine may make you sweat less, causing your body to overheat.

Tell your doctor if you are likely to be exposed to organophosphorous pesticides.

The risk of you experiencing a toxic reaction to the pesticide may be increased while you are taking Aldazine.

If you have not told your doctor about any of the above, tell them before you start taking Aldazine.

Taking other medicines

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

Do not take Aldazine with other antipsychotic medicines used to treat mental illnesses.

Other medicines which may interfere with Aldazine or be affected by Aldazine include:

- * a variety of medicines which can increase and prolong the effects of Aldazine potentially causing a fatal heart rhythm disturbance, including fluoxetine, paroxetine, moclobemide, fluvoxamine, cimetidine, pindolol and propranolol
- * medicines used to treat other mental illnesses such as depression and mood swings, including lithium, monoamine oxidase inhibitors and tricyclic antidepressants
- * benzodiazepines and other medicines used to treat anxiety or help you sleep
- * pain killers
- * antihistamines, medicines used to prevent or relieve the symptoms of allergy such as hay fever
- * anticonvulsants, medicines used to control epilepsy
- * warfarin, a medicine used to prevent blood clots
- * some diuretics (fluid tablets)
- * medicines used to treat diabetes

- * medicines used to treat high blood pressure and heart conditions, including quinidine and beta blockers
- * atropine, contained in some cough and cold preparations and eye drops
- * anticholinergic medicines used to prevent travel sickness and relieve stomach cramps
- * medicines used to treat Parkinson's disease such as levodopa
- * adrenaline, a medicine used in emergency situations.

Your doctor can tell you what to do if you are taking any of these medicines. You may need to take a different dose or your treatment may need to be changed.

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

Some medicines may interfere with the absorption of Aldazine. These include:

- * medicines used to treat diarrhoea
- * antacids, medicines used to treat stomach ulcers and heartburn.

You can still take these antacids or antidiarrhoea medicines while you are taking Aldazine. However, you must take Aldazine at least two hours before or two hours after taking any of these medicines to make sure there is no problem with absorption.

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

How to take Aldazine

Follow all directions given to you by your doctor or pharmacist carefully

They may differ from the information in this leaflet.

How much to take

Your doctor will tell you how much Aldazine you need to take each day and when to take it.

Ask your doctor or pharmacist for help if you do not understand the instructions on the label.

The usual dose for adults ranges from 50 to 300 mg per day, usually taken in three divided doses. Your doctor may adjust this dose depending on how you respond to this medicine. The maximum recommended dose of Aldazine is 800 mg per day.

If you are elderly, underweight, or have kidney or liver disease, your doctor may start you on a lower dose and increase it more gradually to prevent unwanted effects.

How to take Aldazine

Swallow the tablets with a glass of water.

Aldazine can be taken before or after food.

If you forget to take Aldazine

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

This may increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take Aldazine for

Keep taking Aldazine for as long as your doctor recommends.

Your doctor will check your progress to make sure that Aldazine is working and will discuss with you how long your treatment should continue.

If you take too much Aldazine (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much Aldazine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Aldazine, you may experience dizziness, drowsiness, confusion, nausea or vomiting. You may have a fever, blurred vision, shallow breathing, an irregular heartbeat or fits.

Taking too much Aldazine can lead to a heart attack.

While you are taking Aldazine

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Aldazine.

Some medicines can increase the effects of Aldazine and put you at a greater risk of developing a potentially fatal heart rhythm disturbance if taken together with Aldazine.

Tell your doctor immediately if you start to get heart palpitations (a fast irregular heart beat) which may be accompanied by dizziness or fainting.

These may be signs of a serious heart problem.

Tell your doctor immediately if you notice any uncontrolled movements of the tongue, face, mouth, cheeks, jaw, arms or legs.

These uncontrolled movements may include wormlike movements of the tongue, puffing of the cheeks, puckering of the mouth or chewing movements.

These are symptoms of a very rare condition called tardive dyskinesia, which may develop in people taking Aldazine.

This condition is more likely to occur during long term treatment, especially in elderly women. In very rare cases, this condition is permanent. However, if detected early, it is usually reversible.

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

If you require emergency medical treatment or plan to have surgery, tell your doctor or dentist that you are taking Aldazine.

Aldazine can affect some of the medicines that may be needed, such as adrenaline and general anaesthetics.

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

If you have to have any laboratory tests, tell your doctor that you are taking Aldazine.

Aldazine may affect the results of some tests, including pregnancy tests.

Visit your doctor regularly so that they can check on your progress.

Your doctor may want you to have some blood tests to check your liver and kidney function, an ECG to check the electrical activity of your heart and eye tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not stop taking Aldazine or change the dose, even if you are feeling better, without checking with your doctor.

If you stop taking Aldazine suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To help prevent this, your doctor may gradually reduce the amount of Aldazine you take each day before stopping completely.

Do not use Aldazine to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

Aldazine may cause drowsiness, dizziness or blurred vision in some people, especially at the start of treatment. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Avoid drinking alcohol while you are taking Aldazine.

Combining Aldazine and alcohol can make you drowsy and increase the risk of getting other side effects.

Be careful taking medicines that can cause drowsiness while you are taking Aldazine.

Combining Aldazine and medicines such as antihistamines, sleeping tablets and pain relievers can make you more drowsy or dizzy. Your doctor and pharmacist can give you more information.

Be careful getting up from a sitting or lying position.

Dizziness or lightheadedness may occur, especially when you get up quickly. Getting up slowly may help.

If outdoors, wear protective clothing and use a sunscreen with a high SPF. Do not use a sunlamp or tanning bed.

Aldazine may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn. If your skin does appear to be affected, tell your doctor.

Make sure you keep cool in hot weather and keep warm in cool weather.

Aldazine may affect the way your body reacts to temperature changes. Hot baths or saunas may make you feel dizzy or faint while you are taking this medicine.

Side effects

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

Like all other medicines, Aldazine may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Children and people over 65 years of age may have an increased chance of getting side effects.

Do not be alarmed by this list 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:

- * drowsiness, dizziness or spinning sensation
- * confusion or disorientation at night, especially in older people
- * dry mouth, feeling sick, vomiting, loss of appetite
- * diarrhoea or constipation
- * weight changes
- * headache
- * restlessness, agitation, depression, excitement
- * difficulty sleeping, vivid dreams
- * blurred vision, brownish colouring of vision, difficulty focussing especially at night
- * painful swollen breasts, unusual secretion of breast milk
- * changes in menstrual periods

- * impaired sexual function in men
- * pale skin
- * stuffy nose.

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

- * fast or irregular heart beat (palpitations), sometimes with dizziness or fainting
- * sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing
- * symptoms of sunburn (redness, itching, swelling or blistering of the skin) which occur more quickly than normal
- * sudden increase in body temperature, with sweating, fast heartbeat, muscle stiffness and changes in blood pressure, which may lead to coma
- * trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk
- * sudden spasms of the muscles in the eye, head, neck or body
- * uncontrolled movements of the tongue, face, mouth, cheeks, jaw, arms or legs
- * bleeding or bruising more easily than normal
- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * convulsions (fits)
- * disturbed thinking, hallucinations (seeing or hearing things that are not there)
- * severe stomach pain, often with bloating, cramps or vomiting
- * swelling of the ankles or feet
- * yellowing of the skin or eyes
- * dark coloured urine
- * difficulty passing urine
- * loss of control of your bladder
- * persistent painful erection.

The above side effects are serious and require medical attention.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Aldazine

Storage

Keep Aldazine 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.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Aldazine or any other medicine in the bathroom or near a sink.

Do not leave Aldazine in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Aldazine tablets are available in 4 strengths:

- * Aldazine 10 - round, light green tablet
- * Aldazine 25 - round, light brown tablet, marked "TZ/25" on one side and a Greek alpha symbol on the other.

- * Aldazine 50 - round, light green tablet, marked "TZ/50" on one side and a Greek alpha symbol on the other.
- * Aldazine 100 - round, dark green tablet, marked "TZ/100" on one side and a Greek alpha symbol on the other.

Each bottle contains 100 tablets.

Each blister pack contains 90 tablets.

Ingredients

The active ingredient in Aldazine is thioridazine hydrochloride. Each Aldazine tablet contains 10 mg, 25mg, 50 mg or 100 mg of thioridazine hydrochloride.

Aldazine 10 mg tablets also contain:

- * lactose
- * microcrystalline cellulose
- * pregelatinised maize starch
- * dextrates
- * sodium starch glycollate
- * colloidal anhydrous silica
- * purified talc
- * magnesium stearate
- * hypromellose
- * diethyl phthalate [bottles only]
- * carnauba wax [bottles only]
- * ethylcellulose [bottles only]
- * hydroxypropylcellulose [bottles only]
- * titanium dioxide CI 77891 (E171)
- * quinoline yellow CI 47005 (E104)
- * brilliant blue FCF CI 42090 (E133)
- * sunset yellow FCF CI 15985 (E110).

Aldazine 25 mg tablets also contain:

- * microcrystalline cellulose
- * pregelatinised maize starch
- * dextrates
- * sodium starch glycollate
- * colloidal anhydrous silica
- * purified talc

- * magnesium stearate
- * hypromellose
- * diethyl phthalate
- * ethylcellulose
- * hydroxypropylcellulose
- * iron oxide yellow CI 77891 (E172)
- * iron oxide red CI 77491(E172)
- * iron oxide black CI 77499 (E172).

Aldazine 50 mg and 100 mg tablets also contain:

- * microcrystalline cellulose
- * pregelatinised maize starch
- * dextrates
- * sodium starch glycollate
- * colloidal anhydrous silica
- * purified talc
- * magnesium stearate
- * hypromellose
- * diethyl phthalate
- * carnauba wax [50 mg tablets only]
- * lactose [100 mg tablets only]
- * ethylcellulose [100 mg tablets only]
- * titanium dioxide CI 77891 (E171)
- * quinoline yellow CI 47005 (E104)
- * brilliant blue FCF CI 42090 (E133)
- * sunset yellow FCF CI 15985 (E110).

Aldazine tablets are gluten free.

Manufacturer

Aldazine is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

- * Aldazine 10 mg bottle
AUST R 17568
- * Aldazine 10 mg blister pack
AUST R 93654
- * Aldazine 25 mg bottle
AUST R 53177
- * Aldazine 25 mg blister pack
AUST R 53178
- * Aldazine 50 mg bottle
AUST R 17571
- * Aldazine 50 mg blister pack
AUST R 17597
- * Aldazine 100 mg bottle
AUST R 49813
- * Aldazine 100 mg blister pack
AUST R 49814

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