Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hydrene.

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 benefits and risks. Your doctor has weighed the risks of you taking Hydrene against the benefits they expect it will have 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 Hydrene is used for

Hydrene is used to:

- decrease swelling (oedema) of the ankles, feet, legs or abdomen due to fluid build-up. This can be caused by some heart, liver or kidney conditions, or the use of certain medicines (e.g. corticosteroids or oestrogen); sometimes, the origin of the swelling can be unknown
- lower high blood pressure (hypertension)

Hydrene is a fluid tablet or diuretic. It works by making your kidneys pass more water and salt while at the same time, helping to maintain normal potassium levels in the blood. This helps reduce the amount of excess fluid in the body.

Hydrene may be taken alone or in combination with other medicines to treat your condition.

Your doctor may have prescribed Hydrene for another reason. Ask your doctor if you have any questions about why Hydrene has been prescribed for you.

Hydrene is available only with a doctor's prescription.

There is no evidence that Hydrene is addictive.

Before you take Hydrene

When you must not take it

Do not take Hydrene if you are allergic to medicines containing either triamterene or hydrochlorothiazide or any of the ingredients listed at the end of this leaflet.

Do not take Hydrene if you have an allergy to sulfonamide (sulfa) medicines, such as some antibiotics (e.g. sulfonamide antibiotics).

Hydrochlorothiazide, one of the active ingredients of Hydrene, is a sulfonamide-containing medicine. If you are allergic to sulfonamide medicines, such as certain antibiotics, you are likely to be allergic to Hydrene.

Check with your doctor or pharmacist if you are not sure if you have an allergy to sulfonamide-containing medicines. Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Hydrene if you have:

- certain kidney problems
- no production or passing of urine

- high potassium levels in your blood (hyperkalaemia), possibly due to a high potassium diet, taking potassium supplements, or other potassium-conserving medication
- liver problems.

Do not take Hydrene if you are pregnant or intend to become pregnant.

Like most diuretic medicines, Hydrene is not recommended for use during pregnancy.

Do not take Hydrene if you are breastfeeding or plan to breastfeed.

Hydrene passes into breast milk and may affect your baby.

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

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

Do not give Hydrene to children.

The safety of Hydrene in children has 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

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

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

- high blood sugar (diabetes)
- · kidney problems
- · liver problems
- · heart problems
- gout or hyperuricaemia
- high cholesterol levels
- systemic lupus erythematosus (SLE)

Your doctor may want to take special care if you have any of these conditions.

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

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.

Some medicines may be affected by Hydrene, or may affect how well it works. These include:

- potassium supplements or salt-substitutes which contain potassium
- certain fluid tablets (diuretics)
- medicines used to treat high blood pressure and certain heart or kidney conditions, including angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor antagonists, methyldopa and hydralazine
- medicines used to treat some types of mental illness, including lithium, monoamine oxidase inhibitors (MAOIs) and phenothiazines

- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis. This includes non-steroidal anti-inflammatory drugs (NSAIDs) such as indomethacin (e.g. Indocid, Arthrexin), ibuprofen (e.g. Nurofen, Rafen), naproxen (e.g. Naprosyn, Inza), and coxibs such as celecoxib (e.g. Celebrex)
- methotrexate, a medicine used to treat arthritis and some types of cancers
- strong pain killers such as codeine, morphine and dextropropoxyphene
- digoxin, a medicine used to treat heart failure
- medicines used to relax muscles before or during surgery
- insulin and tablets used to treat diabetes
- adrenaline and noradrenaline, medicines used in emergency situations such as an allergic reaction

Your doctor can tell you what to do if you are taking any of these medicines.

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

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

How to take Hydrene

How much to take

For high blood pressure, the usual starting dose is one tablet daily.

For fluid retention, the usual starting dose is one tablet twice daily.

Your doctor may advise you to take a different dose. This depends on your condition and whether or not you are taking any other medicines

Your doctor may change your dose if necessary. The maximum dose is four tablets a day.

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

How to take Hydrene

Swallow the tablets with a glass of water.

Hydrene tablets can be broken in half if your doctor has prescribed half a tablet.

When to take Hydrene

Take Hydrene at about the same time each day after meals.

If you are taking Hydrene once a day, take it in the morning, for example, at breakfast time.

Hydrene takes about one hour to start working.

If you are taking more than one dose a day, take the last dose no later than 6 p.m, unless your doctor tells you otherwise.

Hydrene may increase the amount of water (urine) you pass and also the number of times you go to the toilet. By taking the last dose no later than 6 p.m there may be less chance of your sleep being disturbed.

If you forget to take Hydrene

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.

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

If you have any questions about this, check with your doctor or pharmacist.

How long to take Hydrene for

It is important to take Hydrene as instructed by your doctor as it helps control your condition and lower the fluid build up in your body.

Keep taking Hydrene for as long as your doctor recommends.

If you take too much Hydrene (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 Hydrene. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Hydrene, you may feel weak, thirsty, tired, confused, dizzy, nausea, vomiting, have a flushed face, muscle cramps and a very fast heart rate.

While you are taking Hydrene

Things you must do

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

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

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

Tell your doctor if you have any of the following symptoms:

- excessive vomiting or diarrhoea
- · dry mouth, thirst
- weakness, tiredness, drowsiness
- muscle pain or cramps
- fast heart beat
- passing less urine than normal.

You may be dehydrated from losing too much water if you experience any of these symptoms.

Make sure you drink enough water during exercise and hot weather when you are taking Hydrene, especially if you sweat a lot. If you do not drink enough water while taking Hydrene, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Tell your doctor if you have excessive vomiting and/or diarrhoea while taking Hydrene.

This can also mean that you are losing too much water and salt, and as a result, your blood pressure may drop too much.

If you plan to have surgery that needs a general anaesthetic, including dental surgery, tell your doctor or dentist that you are taking Hydrene.

Your blood pressure may drop suddenly.

If you have to have any blood tests, tell your doctor that you are taking Hydrene.

Hydrene may affect the results of some tests.

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

Your doctor may want to check your blood pressure and potassium levels regularly to make sure Hydrene is working properly.

Things you must not do

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

Do not let yourself run out of Hydrene over the weekend or on holidays.

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

Do not give Hydrene 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 Hydrene affects you. Hydrene may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. If this problem gets worse or continues, talk to your doctor.

Be careful when drinking alcohol or taking strong pain killers while taking Hydrene.

Combining Hydrene with alcohol or strong pain killers can make you more dizzy or lightheaded.

Be aware of foods or drinks that have a high potassium content.

Hydrene helps to maintain normal potassium levels in your body. However, if you eat foods or have drinks that are high in potassium this may lead to an increase of potassium in your body. Too much potassium can be harmful, therefore it is important to discuss your diet with your doctor or pharmacist.

Salt-substitutes used at the table or for cooking also contain potassium and should therefore be avoided.

Check your blood sugar levels carefully if you are a diabetic.

Hydrene may change how well your diabetes is controlled. Your doses of diabetic medicines, including insulin, may need to change.

Side effects

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

Like all other medicines, Hydrene 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.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be a larmed 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:

- dizziness or light-headedness
- · fatigue, lack of energy
- nausea, vomiting
- diarrhoea or constipation
- blurred vision

- impotence
- headache.

Tell your doctor as soon as possible if you notice any of the following:

- · very dry mouth or unusual thirst
- · weakness, muscle pain or cramps
- numbness or tingling in the hands or feet
- · irregular heart beat
- mental confusion
- · passing little or no urine
- swollen or painful joints due to gout
- severe upper stomach pain, often with nausea and vomiting
- symptoms of sunburn (redness, itching, swelling or blistering of the skin) which occur more quickly than normal
- yellowing of the skin or eyes (jaundice)
- looking pale, tiredness, being short of breath when exercising (anaemia)
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal.

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

- rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

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

After taking Hydrene

Storage

Keep Hydrene 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 the pack until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below $30^{\circ}C$.

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

Do not leave Hydrene in the car or on window sills.
Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Hydrene, 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

Hydrene is a round, yellow, scored tablet marked 'T' over 'H' on one side and an alpha symbol on the reverse

Each pack contains 100 tablets.

Ingredients

Hydrene contains two active ingredients:

- triamterene 50 mg
- hydrochlorothiazide 25 mg

The tablets also contain the following inactive ingredients:

- lactose
- starch maize
- cellulose microcrystalline
- povidone
- disodium edetate
- sodium starch glycollate
- talc purified
- magnesium stearate
- sunset yellow FCF CI15985

The tablets are gluten free.

Sponsor

Hydrene is supplied 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 Number Hydrene - AUST R 42228

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