

Hysone 4; Hysone 20

contains the active ingredient hydrocortisone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hysone.

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 Hysone 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 Hysone is used for

Hysone belongs to a group of medicines called corticosteroids. Hysone contains hydrocortisone, which is a hormone produced by the adrenal glands, small glands that sit near the top of the kidneys.

Hysone is used to replace the hydrocortisone in patients whose adrenal glands do not produce enough naturally. This occurs in conditions such as Addison's disease or when the adrenal glands are damaged or not working properly.

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

Hysone is available only with a doctor's prescription.

There is no evidence that Hysone is addictive.

Before you take Hysone

When you must not take it

Do not take Hysone if you are allergic to medicines containing hydrocortisone or any of the ingredients listed at the end of this leaflet.

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 Hysone if the expiry date (Exp.) printed on the pack has passed.

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

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 are pregnant or plan to become pregnant.

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

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

Hysone passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Hysone when breastfeeding.

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

- current or recent infection, including tuberculosis, chicken pox, herpes, measles or infection in the eye
- high blood pressure
- recent heart attack, heart failure
- kidney problems
- liver problems, including cirrhosis
- stomach or duodenal ulcers
- inflammation of the colon
- diabetes mellitus
- blood clotting problems
- osteoporosis or other bone diseases
- chronic back problems
- convulsive disorders, such as epilepsy
- underactive thyroid
- Cushing's syndrome
- cancer that has spread or is spreading
- mental illness
- skin rashes.

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

Tell your doctor if you plan to have surgery.

Your doctor may need to keep an eye on any changes to your condition caused by stress from the surgery. This may lead to adjustments to your dose.

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

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 Hysone, or may affect how well it works. These include:

- oral contraceptives (birth control pill)
- medicines used to treat epilepsy, such as phenytoin and barbiturates
- rifampicin, an antibiotic used to treat and prevent infections
- diuretics, also called fluid tablets
- digoxin, a medicine used to treat heart conditions
- aspirin
- live vaccines
- insulin or oral medicines for diabetes.

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 Hysone.

How to take Hysone

How much to take

The dose varies from patient to patient.

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

Any changes to your condition during therapy may also require your doctor to adjust your dose.

Tell your doctor if you believe that your condition is either getting better or worse.

You may require adjustments to your dose.

Tell your doctor if you feel that your current dose is not as effective as before.

Your doctor will review your situation and may recommend a dose adjustment.

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

How to take it

Swallow the tablets with a glass of milk, or take Hysone with food.

This will lessen the chance of a stomach upset.

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 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 it for

Keep taking Hysone for as long as your doctor recommends.

If treatment is to be stopped after more than a few days treatment, your doctor will reduce your dose gradually.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and

Emergency at the nearest hospital, if you think you or anyone else may have taken too much Hysone. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Hysone, you may have symptoms of weakness, dizziness, convulsions, headache, nausea, vomiting and blurred vision.

While you are taking Hysone

Things you must do

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

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

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

Discuss with your doctor situations in which it may be appropriate for you to make short-term changes of dose during illness, or at a time of medical or dental procedures.

Illness or medical or dental procedures can bring on stress, which may affect your condition and require temporary dose increases.

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

You will need to have regular blood tests to measure your potassium and calcium levels. If your levels are low, you may need to take dietary supplements.

Have your blood pressure checked regularly.

Hysone may increase your blood pressure due to an increase in the amount of salt in your body. You may need to restrict the amount of salt in your diet.

If you have to have any other tests, such as allergy skin tests,

tell your doctor that you are taking Hysone.

Hysone may affect the results of some tests.

Things you must not do

Do not stop taking Hysone without checking with your doctor. Stopping Hysone suddenly may cause unwanted side effects. Your doctor will want you to gradually reduce the amount of Hysone you are taking before stopping completely.

Do not have any vaccinations without first checking with your doctor.

If you are taking Hysone vaccines may not work as well and there is an increased risk of complications.

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

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

Things to be careful of

Avoid contact with people who have infections, such as chicken pox, measles or herpes.

Infections are easier to get and harder to spot while you take Hysone.

Tell your doctor immediately if you think you may have picked up an infection while taking Hysone.

Infections can bring on stress, which may affect your condition and require temporary dose adjustments.

If you are a diabetic, monitor your blood sugar levels regularly.

Your doctor may need to adjust your dose of insulin or tablets.

Side effects

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

Like all other medicines, Hysone 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 or are a postmenopausal woman, you may have an increased chance of getting side effects.

Long term therapy with Hysone may affect your bone density, making you more likely to get fractures or osteoporosis.

In children, Hysone may slow or stop their growth especially if it is used for a long time. Your child's doctor will discuss the risks and benefits involved.

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:

- nausea
- increased appetite, weight gain
- dizziness
- headaches
- insomnia (trouble sleeping)
- skin rashes, acne or blotchy skin
- thin fragile skin
- bruising or bleeding more easily than normal, purplish-blue spots or lines under the skin
- facial redness
- increase in body or facial hair
- increased sweating
- irregular menstrual periods.

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

- severe upper stomach pain with nausea and vomiting
- fits or convulsions, loss of consciousness
- weakness, loss of muscle mass
- wounds that will not or take longer to heal

- increased thirst and frequent urination
- severe indigestion with stomach pain and discomfort
- signs of infection such as fever, chills, sore throat or mouth ulcers
- blurred vision, changes in vision
- swelling of the face, hands, ankles or feet
- confusion, hallucinations, depression or mood swings
- swelling and redness along a vein which is tender to touch.

Your doctor may decide to alter your dose to help control serious side effects and organise certain tests to monitor the above effects.

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 Hysone

Storage

Keep Hysone 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 bottle until it is time to take them.

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

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

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Hysone, 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

Hysone comes in 2 strengths of tablets:

- Hysone 4 round, white, scored tablet marked H/4 on one side and G on the reverse. Each bottle contains 50 tablets.
- Hysone 20 round, white, scored tablet marked H/20 on one side and G on the reverse. Each bottle contains 60 tablets.

Ingredients

The active ingredient in Hysone is hydrocortisone.

- each Hysone 4 tablet contains 4 mg of hydrocortisone
- each Hysone 20 tablet contains 20 mg of hydrocortisone.

The 4 mg tablets also contain:

- lactose monohydrate
- povidone
- maize starch
- magnesium stearate.

The 20 mg tablets also contain:

- lactose monohydrate
- povidone
- maize starch
- magnesium stearate
- macrogol 8000.

Sponsor

Hysone is supplied by:

Alphapharm Pty Limited
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
ABN 93 002 359 739
www.mylan.com.au
Medical Information
Phone: 1800 028 365

Australian registration numbers:

Hysone 4 - AUST R 27923

Hysone 20 - AUST R 27926

This leaflet was prepared on 09
May 2017.