

HYSONE[®] 4; HYSONE[®] 20

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using HYSONE?

HYSONE contains the active ingredient hydrocortisone. 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.

For more information, see Section [1. Why am I using HYSONE?](#) in the full CMI.

2. What should I know before I use HYSONE?

Do not use if you have ever had an allergic reaction to hydrocortisone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use HYSONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HYSONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use HYSONE?

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

More instructions can be found in Section [4. How do I use HYSONE?](#) in the full CMI.

5. What should I know while using HYSONE?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using 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.
- Visit your doctor regularly so they can check on your progress.
- Have your blood pressure checked regularly.
- If you have to have any other tests, such as allergy skin tests, tell your doctor that you are taking HYSONE.

Things you should not do	<ul style="list-style-type: none">• Do not stop taking HYSONE without checking with your doctor• Do not have any vaccinations without first checking with your doctor.• 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.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 30°C.• Keep your tablets in the bottle until it is time to take them.

For more information, see Section [5. What should I know while using HYSONE?](#) in the full CMI.

6. Are there any 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.

In children, HYSONE may slow or stop their growth especially if it is used for a long time. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

HYSONE 4; HYSONE 20

Active ingredient(s): *hydrocortisone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using HYSONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HYSONE.**

Where to find information in this leaflet:

- [1. Why am I using HYSONE?](#)
- [2. What should I know before I use HYSONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use HYSONE?](#)
- [5. What should I know while using HYSONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using HYSONE?

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

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.

2. What should I know before I use HYSONE?

Warnings

Do not use HYSONE if:

- you are allergic to hydrocortisone, or any of the ingredients listed at the end of this leaflet.
 - Always check the ingredients to make sure you can use this medicine.
 - 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.
- the expiry date (Exp.) printed on the pack has passed.

- the packaging shows signs of tampering or the tablets do not look quite right.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- 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.

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with HYSONE and affect how 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HYSONE.

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

4. How do I use 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 HYSONE

- 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 use HYSONE

If you miss your dose at the usual time, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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.

If you use too much HYSONE

If you think that you have used too much HYSONE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using HYSONE?

Things you should 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 should 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.

Looking after your medicine

- 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.

Follow the instructions on the label on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● nausea● increased appetite, weight gain● dizziness● headaches● insomnia (trouble sleeping)● skin rashes, acne or blotchy skin	Tell your doctor if you notice any of the following and they worry you

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p>Tell your doctor as soon as possible if you notice any of the following</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What HYSONE contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">● each HYSONE 4 tablet contains 4 mg of hydrocortisone● each HYSONE 20 tablet contains 20 mg of hydrocortisone.
Other ingredients (inactive ingredients)	The 4 mg tablets also contain: <ul style="list-style-type: none">● lactose monohydrate● povidone

	<ul style="list-style-type: none"> • maize starch • magnesium stearate. <p>The 20 mg tablets also contain:</p> <ul style="list-style-type: none"> • lactose monohydrate • povidone • maize starch • magnesium stearate • macrogol 8000.
Potential allergens	HYSONE contains sulfites and sugars as lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What HYSONE looks like

HYSONE 4 round, white, scored tablet marked H/4 on one side and G on the reverse. Each bottle contains 50 tablets. (AUST R 27923)

HYSONE 20 round, white, scored tablet marked H/20 on one side and G on the reverse. Each bottle contains 60 tablets. (AUST R 27926)

Who distributes HYSONE

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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