

## Hydrocortisone

*hydrocortisone*

5 mg and 20 mg Tablets

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### What is in this leaflet

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**Please read this leaflet carefully before you start taking Hydrocortisone.**

This leaflet answers some common questions about Hydrocortisone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Hydrocortisone against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine. You may need to read it again.**

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### What Hydrocortisone is used for

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Hydrocortisone Tablets contains the active ingredient hydrocortisone. It belongs to a group of medicines called corticosteroids. These are used to replace adrenal hormones you may be lacking in your body.

Hydrocortisone is used in replacement therapy of an inactive or underactive adrenal gland for example: Addison's disease.

Hydrocortisone is used to inhibit ACTH (hormone) secretion when taken in conjunction with aminoglutethimide for breast cancer and cancer of the prostate.

Your doctor may have prescribed Hydrocortisone for another reason.

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

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

Hydrocortisone is not addictive.

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### Before you take Hydrocortisone

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#### ***When you must not take it***

**Do not take Hydrocortisone if you have an allergy to:**

- any medicine containing hydrocortisone
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

**Do not take Hydrocortisone if:**

- you have an infection
- you have been vaccinated recently or are going to have any live vaccinations.

**Do not take it after the expiry date (EXP) printed on the back.** If you take it after the expiry date has passed, it may not work as well.

**Do not take it if the packaging is torn or shows signs of tempering.**

**If you are not sure whether you should start taking Hydrocortisone, talk to your doctor.**

***Before you start to take it***

**Tell your doctor if:**

**1. you have allergies to:**

- any other medicines including hydrocortisone
- any other substances, such as foods, preservatives or dyes.

**2. you are exposed to shingles, chickenpox or measles.**

It is important to avoid exposure to people who have shingles or chickenpox, especially if you have not already had these illnesses or are not sure if you have had them.

**3. you have, or any of your close family, ever had severe mood disorder. This includes having had symptoms of mood-related disorders in the past while taking steroid medicines like Hydrocortisone Tablets.**

Mental health problems can occur while taking steroids like hydrocortisone

- usually they start within a few days or weeks of starting the medicine
- risk may be higher with high doses
- most of these problems recover if the dose is lowered or the medicine is stopped.

**4. you have, or have had, the following medical conditions:**

- osteoporosis (thinning of bones)
- high blood pressure
- diabetes or a family history of diabetes
- tuberculosis (TB)
- glaucoma
- muscle weakness with steroids
- liver problems
- kidney problems
- epilepsy or seizure (fits) disorder
- peptic ulcer (stomach ulcer)
- heart problems including recent heart attacks
- thyroid problems.

**5. you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits involved before taking the tablets.

**6. you are breastfeeding or planning to breastfeed.**

Hydrocortisone may pass into breastmilk. Your doctor can discuss with you the risks and benefits involved before taking the tablets.

**7. you have intolerance to some sugars.**

Hydrocortisone tablets contain lactose.

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

***Taking other medicines***

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Hydrocortisone.**

Some medicines may interfere with Hydrocortisone. These include:

- live vaccines
- medicines used to treat epilepsy such as phenytoin, phenobarbital, carbamazepine and primidone
- antibiotics used to treat tuberculosis (TB) such as rifabutin and rifampicin
- aminoglutethimide, a medicine used in the treatment of cancer
- St John's Wort
- medicines used in the treatment of HIV infections such as ritonavir, efavirenz, nevirapine and cobicistat.
- mifepristone, a medicine used to assist medical termination of pregnancy
- medicines used to treat fungal infections such as amphotericin, ketoconazole, itraconazole, pesaconazole and vericonazole

- antibiotics such as erythromycin, telithromycin and clarithromycin
- grapefruit juice
- oestrogen-containing medicines
- growth hormone somatropin
- medicines for diabetes including insulin
- diuretics (water tablets)
- anticoagulants (blood thinners) such as warfarin
- salicylates such as aspirin
- non-steroidal anti-inflammatory drugs (NSAIDs)
- theophylline
- medicines sometimes used for asthma, low blood pressure or in cough and cold remedies called sympathomimetics
- digoxin, a medicine used to treat heart failure and irregular heartbeat
- methotrexate, a medicine used for psoriasis or cancer.

These medicines may be affected by Hydrocortisone, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Hydrocortisone.

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## How to take Hydrocortisone

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### *How much to take*

**Always take this medicine exactly as your doctor told you. Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

The amount you take each day will depend on your illness. If you take the wrong dose, Hydrocortisone may not work as well and your problem may not improve.

### *How to take it*

**Swallow the tablet with a glass of water.**

### *When to take it*

**Take Hydrocortisone at about the same time each day.**

Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

Hydrocortisone can be taken with or without food.

### *How long to take it*

**Do not stop taking this medicine just because you feel better. You must follow your doctor's instructions on stopping these tablets.**

Your doctor may want you to reduce gradually the number of tablets before you finally stop taking them. Never let your tablets run out before receiving the next prescription. It may be dangerous to stop treatment without your doctor's advice.

### *If you forget to take it*

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of unwanted side effects.

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

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## While you take Hydrocortisone

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### *Things you must do*

**See your doctor if you think you may have an infection.** Taking hydrocortisone for a long period of time increases your chance of getting infections.

**Stay away from anyone you know with:**

- chickenpox
- shingles
- measles

**You must tell your doctor if you are taking or have recently taken Hydrocortisone Tablets and**

**you become ill, experience fever, suffer stress, get injured or are about to have a surgical procedure.** Your dose of hydrocortisone may need to be changed accordingly by your doctor.

**Tell your doctor immediately if you become pregnant while you are taking the medicine.**

**Tell your doctor and pharmacist that you are taking this medicine if you are about to be started on any new medicine.**

### ***Things you must not do***

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

**Do not stop taking Hydrocortisone, or lower the dosage, without checking with your doctor.**

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as low blood pressure which may be felt as dizziness or light-headedness, fever, muscle weakness, joint pain, runny or blocked nose, conjunctivitis, painful itchy skin, and weight loss.

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Hydrocortisone affects you.** It may cause dizziness or blurred vision in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

**Be careful if you are over 65.** Hydrocortisone Tablets should be taken with caution in the elderly as they usually have an increased sensitivity to side effects.

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## **In case of overdose**

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***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Hydrocortisone.**

**Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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## **Side effects**

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

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 adverse effects.

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

**Do not be alarmed by this list of possible adverse effects.** You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**If any of the following happen, stop taking Hydrocortisone and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

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

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Hydrocortisone. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Hydrocortisone can cause mental health problems. These side effects are common (between 1 in 10 and 1 in 100 people are affected).

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

- feeling depressed, including thinking about suicide
- being irritable and anxious
- experiencing mood fluctuation and sleeping disturbances
- feeling, seeing or hearing things which do not exist
- having difficulty in thinking or being confused and losing your memory.

**Other side effects**

(Frequency unknown as cannot be estimated from the available data)

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

- infections. Some fungal and viral infections, including herpes, may be activated.
- development of Cushingoid facies (round or moon-shaped face)
- increased blood sugar levels/diabetes
- salt and water retention (causing swelling and raised blood pressure)
- increased appetite and weight gain
- worsening of epilepsy
- sleepiness, dizziness/spinning sensation, headache
- changes in vision as a result of cataracts (clouding of the lens in the eye) or glaucoma (increased pressure inside the eye), blurred vision, dry eyes, thinning of the surface of the eye, existing eye infections may get worse including some fungal and viral infections
- increased damage to the heart in the event of a heart attack, high blood pressure and formation of blood clots
- gastrointestinal symptoms such as indigestion, stomach or food-pipe ulcers, bloated feeling, abdominal pain, thrush, and tooth decay.

- skin-related symptoms such as slow healing of wounds or cuts, acne, bruising, stretch marks, spider veins, and excessive hair
- bone, muscle and joints symptoms such as muscle weakness, joint swelling and bones thinning which can lead to fractured or broken bones.
- irregular or lack of menstrual periods.
- generally feeling unwell and tiredness.

**Tell your doctor if you notice any other effects.**

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

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## After taking Hydrocortisone

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### *Storage*

**Keep your tablets in the dispensing 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 at or below 30°C.

**Do not store Hydrocortisone in the bathroom or near a sink. Do not leave it in the car or on a windowsill.** Heat and dampness can destroy some medicines.

**Keep it 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*

**Return any unused medicine to your pharmacist.**

If your doctor tells you to stop taking this medicine or they have passed their expiry date, ask your pharmacist what to do with any unused medicine.

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## Product description

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### *What it looks like*

**Hydrocortisone 5 mg Tablets** are white, round, biconvex tablet having a diameter of 6.5 mm. Available in a plastic bottle containing 100 tablets

**Hydrocortisone 20 mg Tablets** are white, round, biconvex tablet having a diameter of 7.94 mm, breakline score line on one face and dp logo on the other. Available in a plastic bottle containing 100 tablets

### ***Ingredients***

Active ingredient(s):

- Hydrocortisone

Inactive ingredients:

- Lactose monohydrate
- Magnesium stearate
- Maize starch
- Povidone
- Purified talc

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## **Sponsor details**

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Hydrocortisone is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

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## **Date of preparation**

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28 November 2017

(based on data sheet dated 28 November 2017)