

# CORTATE tablets

## 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 CORTATE?

CORTATE contains the active ingredient cortisone acetate. CORTATE is used in the treatment of many different conditions, including severe allergic reactions, asthma, itchy skin rashes, chronic inflammatory diseases and auto-immune diseases.

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

### 2. What should I know before I use CORTATE?

Do not use if you have ever had an allergic reaction to cortisone acetate 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 CORTATE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with CORTATE 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 CORTATE?

- The dosage varies depending on your condition. Your doctor will advise you.
- Swallow the tablets with a glass of water.

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

### 5. What should I know while using CORTATE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, surgeon, dentist or pharmacist you visit that you are using CORTATE.</li><li>• Tell your doctor if you get a serious infection or injury.</li><li>• Tell your doctor immediately if you are diabetic and if you notice any change in your blood or urine sugar readings.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop or lower the dosage of this medicine suddenly without checking with your doctor.</li><li>• Do not have any 'live' immunisations such as measles, oral polio or yellow fever, without checking with your doctor.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the bottle until it is time to take them.</li><li>• Store in a cool dry place protected from light, where the temperature stays below 30°C and keep out of reach of children.</li></ul>

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

### 6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur. When CORTATE is taken for short periods of time, even at high doses, it is unlikely to produce harmful effects. However, the risk of side effects is greater when CORTATE is taken for long periods of time and in high doses.

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.

# CORTATE tablets

Active ingredient: *cortisone acetate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using CORTATE. **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 CORTATE.**

Where to find information in this leaflet:

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

## 1. Why am I using CORTATE?

CORTATE contains the active ingredient cortisone acetate. CORTATE belongs to a group of medicines called corticosteroids which is a synthetic version of a naturally occurring cortisol hormone secreted by the adrenal glands in your body.

CORTATE is used in the treatment of many different conditions, including severe allergic reactions (such as reactions to drugs), severe asthma, severe itchy skin rashes, chronic inflammatory diseases and 'auto-immune' diseases.

CORTATE is only able to prevent or reduce symptoms of your condition; it does not cure it. Individuals will vary greatly in their response to CORTATE. Your doctor will check your progress at regular intervals.

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

Your doctor may have prescribed this medicine for another reason.

## 2. What should I know before I use CORTATE?

### Warnings

**Do not use CORTATE if:**

- you are allergic to cortisone acetate or any of the ingredients listed at the end of this leaflet.
- you have an uncontrolled infection.

**Check with your doctor if you have allergies to:**

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

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.**

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

The active ingredient in CORTATE passes into breast milk and therefore there is a possibility that the breastfed baby may be affected. Your doctor can discuss with you the risks and benefits involved.

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

- liver disease
- stomach ulcer or other intestinal or stomach problems
- kidney disease
- high blood pressure
- muscle weakness
- epilepsy
- diabetes mellitus (sugar diabetes)
- osteoporosis (thinning or softening of the bone)
- thyroid disease
- glaucoma (high pressure in the eyes)
- a current serious or uncontrolled infection
- cataracts
- alcoholism
- heart problems
- tuberculosis
- emotional instability or psychotic tendencies.

It may not be safe for you to take CORTATE if you have any of these medical 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.

### Use in children

Take special care when giving CORTATE to children. It should only be given under your doctor's supervision.

If possible, children should not be exposed to common childhood illnesses such as chickenpox or measles while they are taking CORTATE. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with 'live' vaccines (e.g. oral polio, BCG tuberculosis, measles, mumps, rubella, yellow fever) against common childhood illness while they

are taking CORTATE, as this may result in severe attacks of these illnesses.

Potentially serious side effects can occur in children and growing teenagers who are taking corticosteroids. Some of these include obesity, slowed growth, osteoporosis (softening of the bones) and changes to the adrenal glands.

### Use in the elderly

Elderly patients may be more sensitive to the effects or side effects of CORTATE.

## 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 CORTATE and affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. These include:

- certain medicines used to treat heartburn and indigestion
- medicines to treat diabetes mellitus (sugar diabetes)
- certain medicines to treat heart failure
- medicines used to help the kidneys get rid of salt and water by increasing the amount of urine produced (diuretics)
- certain medicines used in epilepsy
- medicines used to treat specific infections such as fungal infections or tuberculosis
- potassium supplements
- foods or medicines containing sodium
- medicines to assist in growth
- vaccines/immunisations
- aspirin in certain patients
- medicines used to prevent blood clots
- specific medicines used to prolong labour
- some medicines used for thyroid conditions
- alcohol
- the female hormone, estrogen.

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

CORTATE may influence the results of some laboratory tests.

It may suppress responses to skin tests.

## 4. How do I use CORTATE?

### How much to take

The dosage of CORTATE varies widely and depends on the patient, the condition being treated and the response to the treatment.

Your doctor or pharmacist will tell you how many tablets you will 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.

### When to take CORTATE

How often you take CORTATE depends on what condition is being treated.

**Do not miss any doses and do not stop taking the medicine even if you feel better as this may make your symptoms worse.**

### How to take it

Swallow the tablets with a glass of water.

### How long to take it?

This will depend on your condition and your response to the treatment. Some people will need to take CORTATE for short periods of time whereas other people may require long term therapy.

**Continue taking your medicine for as long as your doctor tells you. Don't stop taking it suddenly because your symptoms may worsen or come back.**

### If you forget to use CORTATE

CORTATE should be used regularly at the same time each day. If you miss a dose at the usual time, the decision of whether you should take it or not will depend on how many times a day your doctor has told you to take CORTATE.

- If you take one dose a day- take the missed dose as soon as possible, then go back to your regular dosing schedule. If you do not remember until the next day, skip the missed dose and do not double the next one.
- If you take several doses a day-take the missed dose as soon as possible, then go back to your regular dosing schedule.
- If you take a dose on alternate days. If you miss a dose and remember it the same morning, take it straight away, then continue as you normally would. If you do not remember the missed dose until later, wait and take it the following morning. Then skip a day before continuing your regular dosage schedule.

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

This may increase the chance of you getting an unwanted side effect.

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

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### **If you use too much CORTATE**

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

#### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), 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.**

## **5. What should I know while using CORTATE?**

### **Things you should do**

#### **Take CORTATE exactly as your doctor has prescribed.**

If you do not follow the doctor's directions, you may not get improvement in the symptoms of your condition. Try not to miss any doses and take the medicine even if you feel well.

#### **Tell your doctor:**

- if your condition returns or worsens after your dose of CORTATE has been decreased or treatment has been stopped.
- you are taking CORTATE before having any skin tests.
- if you get a serious infection or injury.
- or any other doctor, dentist and pharmacist who are treating you that you are taking CORTATE
- if you become pregnant while taking CORTATE.

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking CORTATE.**

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

The trauma of the operation or surgery may mean that your dose of CORTATE needs to be adjusted to cover this stressful time.

**Tell your doctor immediately if you are diabetic and if you notice any change in your blood or urine sugar readings.**

CORTATE may affect your blood sugar levels as it can affect the body's ability to handle glucose. For diabetics, this means that your diabetes may become more severe. For others, diabetes may develop for the first time while taking corticosteroids such as CORTATE.

**Ask your doctor when and how you should stop taking CORTATE.**

If you have been taking CORTATE for a long time, your doctor may gradually decrease the amount you are taking over a period of several days, weeks or months before

stopping it completely. If you have been taking it for a short period of time, this may not apply.

### **Things you should not do**

- **Do not stop taking it or lower the dosage without checking with your doctor or pharmacist.**

If you stop taking CORTATE suddenly, the symptoms of your condition may return or you may develop symptoms of certain hormone deficiencies such as fainting, weakness, restlessness, nausea, vomiting, headache, dizziness, muscle weakness or joint pain.

- **Do not have any immunisations (especially 'live' vaccines such as measles, oral polio or yellow fever) without your doctor's approval while you are taking CORTATE.**
- **Do not give CORTATE to anyone else even if they have the same or a similar condition to you.**
- **Do not take this medicine to treat any other complaints unless your doctor tells you to.**

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

- **Avoid close contact with anyone who has a contagious disease such as chicken pox or measles.**
- **Tell your doctor immediately if you think you have been exposed to chickenpox or measles.**

Exposure to such diseases while you are taking CORTATE, especially if large doses are prescribed, can put you at greater risk of developing these diseases if you have not had them before.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how CORTATE affects you.**

### **Drinking alcohol**

**Check with your doctor or pharmacist before drinking alcohol while you are taking CORTATE.**

If you drink alcohol while taking CORTATE, you may find that you develop stomach problems.

### **Infections**

**You should see your doctor for medical advice for any but the most minor infections.**

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of CORTATE. Infections can bring on stress, which may affect your condition and require temporary dose adjustments.

### **Looking after your medicine**

Keep your tablets in the original container, protected from light, where the temperature stays below 30°C.

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.

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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.

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

### Short term use

When CORTATE is taken for short periods of time, even at high doses, it is unlikely to produce harmful effects.

### Long term use

When CORTATE is taken for long periods of time and in high doses the risk of side effects is greater.

### Less serious side effects

Less serious side effects	What to do
<p><i>General changes to your body:</i></p> <ul style="list-style-type: none"> <li>• slowed growth in children</li> <li>• bloating or rounding of the face</li> <li>• cramps or weakness in the muscles of the arms and legs</li> <li>• water retention leading to swollen legs and feet</li> <li>• irregular heart beat</li> <li>• weight gain</li> <li>• headache</li> <li>• dizziness</li> <li>• irregular menstrual periods.</li> </ul> <p><i>Changes to the immune system:</i></p> <ul style="list-style-type: none"> <li>• an increased seriousness or frequency of infections.</li> </ul> <p><i>Changes to the gastrointestinal system:</i></p> <ul style="list-style-type: none"> <li>• nausea (feeling sick)</li> <li>• vomiting</li> <li>• indigestion, stomach pain or discomfort</li> <li>• increased appetite</li> <li>• diarrhoea or constipation</li> <li>• reduced appetite.</li> </ul> <p><i>Changes in behaviour:</i></p> <ul style="list-style-type: none"> <li>• mood changes</li> <li>• anxiety or nervousness</li> <li>• restlessness</li> <li>• difficulty sleeping (insomnia)</li> <li>• personality changes.</li> </ul> <p><i>Changes to the skin:</i></p> <ul style="list-style-type: none"> <li>• poor wound healing</li> <li>• red or flushed face</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• increased sweating</li> <li>• easy bruising</li> <li>• extra hair growth</li> <li>• acne</li> <li>• red or purple streaks on skin</li> <li>• skin thinning</li> <li>• itchy rash</li> <li>• unusual bleeding or bruising under the</li> </ul> <p><i>Changes in eyes:</i></p> <ul style="list-style-type: none"> <li>• cataracts</li> <li>• eyes sticking out too far</li> <li>• decreased or blurred vision.</li> <li>• skin.</li> </ul>	
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### Other side effects

Some side effects can only be detected by your doctor.

Side effects	What to do
<p>Such side effects can include changes in:</p> <ul style="list-style-type: none"> <li>• strength of bones</li> <li>• blood sugar level (diabetes)</li> <li>• eye pressure (glaucoma)</li> <li>• cholesterol levels</li> <li>• hormone levels</li> <li>• sperm count</li> <li>• blood pressure (hypertension)</li> <li>• certain blood cells</li> <li>• the way nerves work</li> <li>• heart beat and rhythm.</li> </ul>	<p><b>It is important to visit your doctor for regular check ups when CORTATE is taken for long periods of time.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• severe stomach or intestinal pain</li> <li>• sudden changes in your vision</li> <li>• fits</li> <li>• major psychiatric changes</li> <li>• symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat (severe cortisol deficiency)</li> <li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.</li> </ul> <p>Serious side effects are rare.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p> <p>You may need urgent medical attention.</p>

**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](http://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. It is not addictive.

### What CORTATE contains

CORTATE tablets are available in two strengths; 5 mg or 25 mg.

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• Cortisone acetate 5 mg/tablet; or</li><li>• Cortisone acetate 25 mg/tablet</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Lactose monohydrate</li><li>• Povidone</li><li>• Magnesium stearate</li><li>• Maize starch</li><li>• Macrogol 6000 (5 mg tablet only)</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• Sugars as lactose</li></ul>

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

### What CORTATE looks like

The 5 mg tablet is a round, white, flat tablet. Available in bottles of 50 tablets.

The 25 mg tablet is a round, white, flat tablet with a break bar on one side. Available in bottles of 60 tablets.

Australian Registration Numbers:

5 mg tablet: AUST R 27912

25 mg tablet: AUST R 27910

### Who distributes CORTATE

Aspen Pharmacare Australia Pty Ltd

34-36 Chandos St

St Leonards NSW 2065

Australia

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