

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CORTATE. 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 CORTATE 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.

What CORTATE is used for

CORTATE contains cortisone acetate as the active ingredient. It 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.

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.

CORTATE is not addictive.

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

Before you take it

When you must not take it

Do not take CORTATE if you have ever had an allergic reaction to:

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

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.

Do not take it if you have an uncontrolled infection.

Do not take CORTATE after the expiry date (EXP) printed on the pack.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take it if the bottle shows signs of having been tampered with.

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 have allergies to:

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

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.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss the possible risks and benefits of taking this medicine during pregnancy.

Tell your doctor if you are breast-feeding or plan 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.

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

Taking other medicines

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

Some medicines and CORTATE may interfere with each other.

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.

CORTATE may influence the results of some laboratory tests.

It may suppress responses to skin tests.

These medicines may be affected by CORTATE or they 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 will advise you.

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

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.

How to take it

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

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.

How to take it

Swallow the tablets with a glass of water.

When to take it

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 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 take it

If you miss a dose of this medicine, 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 that 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.

What to expect

Individuals will vary greatly in their response to CORTATE. Your doctor will check your progress at regular intervals.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much CORTATE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must 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.

Tell your doctor you are taking CORTATE before having any skin tests.

Tell your doctor if you get a serious infection or injury.

Tell any other doctors, dentists, and pharmacists who are treating you that you are 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.

If you become pregnant while taking CORTATE, tell your doctor or pharmacist.

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 must not do

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.

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.

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.

Things to be aware of

As with any new medicine, you should take care when driving, operating machinery or drinking alcohol until you know how this medicine affects you.

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.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of CORTATE. You should see your doctor for medical advice for any but the most minor infections. Infections can bring on stress, which may affect your condition and require temporary dose adjustments.

Side effects

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

CORTATE helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are elderly you may have an increased chance of getting 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.

Tell your doctor if you notice any of the following and they worry you:

General changes to your body:

- slowed growth in children
- bloating or rounding of the face
- cramps or weakness in the muscles of the arms and legs
- water retention leading to swollen legs and feet
- irregular heart beat
- weight gain
- headache
- dizziness
- irregular menstrual periods.

Changes to the immune system:

- an increased seriousness or frequency of infections.

Changes to the gastrointestinal system:

- nausea (feeling sick)
- vomiting

- indigestion, stomach pain or discomfort
- increased appetite
- diarrhoea or constipation
- reduced appetite.

Changes in behaviour:

- mood changes
- anxiety or nervousness
- restlessness
- difficulty sleeping (insomnia)
- personality changes.

Changes to the skin:

- poor wound healing
- red or flushed face
- increased sweating
- easy bruising
- extra hair growth
- acne
- red or purple streaks on skin
- skin thinning
- itchy rash
- unusual bleeding or bruising under the skin.

Changes in eyes:

- cataracts
- eyes sticking out too far
- decreased or blurred vision.

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

- severe stomach or intestinal pain
- sudden changes in your vision
- fits
- major psychiatric changes
- symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat (severe cortisol deficiency)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Some side effects can only be detected by your doctor. So it is important to visit your doctor for regular check ups when CORTATE is taken for long periods of time.

Such side effects can include changes in:

- strength of bones
- blood sugar level (diabetes)
- eye pressure (glaucoma)
- cholesterol levels
- hormone levels
- sperm count
- blood pressure (hypertension)
- certain blood cells
- the way nerves work
- heart beat and rhythm.

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

Some people may get other side effects while taking CORTATE.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep your tablets in the bottle until it is time to take them.

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

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

Do not store CORTATE or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.

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

Dispose of the tablets where children cannot reach them.

If your doctor or pharmacist tells you to stop taking CORTATE or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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

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.

Ingredients

Active ingredient:

CORTATE 5 mg - 5 mg cortisone acetate per tablet

CORTATE 25 mg – 25 mg cortisone acetate per tablet.

Inactive ingredients:

- lactose monohydrate
- povidone
- magnesium stearate
- maize starch
- macrogol 6000 (5 mg tablet only).

CORTATE tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

Australian Registration Numbers:

5 mg tablet: AUST R 27912

25 mg tablet: AUST R 27910

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