

# Panafcortelone®

Prednisolone

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Panafcortelone. It does not contain all the information that is known about Panafcortelone.

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 Panafcortelone 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 Panafcortelone is used for

Panafcortelone contains prednisolone as the active ingredient. Prednisolone belongs to a group of medicines called corticosteroids which are a synthetic version of a naturally occurring body hormone called cortisol.

Panafcortelone works by entering inflammatory cells and blocking the inflammatory reaction.

This medicine is only able to prevent or reduce symptoms of your condition, it does not cure it.

Panafcortelone is used in the treatment of many different conditions. Some of these conditions include: severe allergies, severe or chronic asthma, skin problems, arthritis, inflammatory diseases of the bowel, cancer and "auto-immune" diseases.

It is also used to prevent or reduce the symptoms of inflammation (such as swelling, redness, pain, tenderness or itching) in any part of the body.

These symptoms can occur in response to injury or can be caused by many different conditions.

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

Your doctor may have prescribed it for another purpose.

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

There is no evidence that it is addictive.

### Before you take it

#### When you must not take it

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

- prednisolone or prednisone
- any of the 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 a current serious or uncontrolled infection, including fungal infections.**

**Do not take Panafcortelone after the expiry date (EXP) printed on the bottle.**

It may have no effect at all or an entirely unexpected effect if you take it after the expiry date.

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

**Do not take this medicine to treat any other complaints unless your doctor has instructed you to do so.**

**Do not give this medicine to anyone else.**

**Before you start to take it**

**Tell your doctor if you are allergic to any other medicines or any foods, dyes or preservatives.**

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

- a current serious or uncontrolled infection, including fungal infections
- recent surgery or serious injury
- diabetes mellitus (sugar diabetes)
- osteoporosis (softening of the bone)
- a stomach ulcer or other stomach or intestinal problems
- liver, kidney or heart disease
- tuberculosis
- epilepsy
- muscle weakness
- glaucoma (high pressure in the eye) or cataracts
- thyroid disease
- high blood pressure.

**Do not take Panafcortelone if you are pregnant or plan to become pregnant.**

It is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

**Do not take it if you are breast feeding or plan to breast feed.**

It is not recommended for use while breast feeding as it is found in breast milk.

**If you have not told your doctor about any of these things, tell them before you take Panafcortelone.**

**Taking other medicines**

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

Some medicines may interfere with Panafcortelone. These include:

- antacids (in large amounts)
- medicines for diabetes
- some medicines for heart disease
- medicines for removal of fluid (diuretics)
- some medicines for epilepsy
- some types of antibiotics
- potassium or salt supplements
- immunisations or vaccines.

These medicines may be affected by Panafcortelone or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking Panafcortelone.

**Use in children**

**Take special care when giving Panafcortelone 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 Panafcortelone. They may suffer from more serious attacks of these illnesses if such exposure occurs.

Children should not be vaccinated with "live" vaccines against common childhood illnesses while they are taking it, 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 bone), and changes to the adrenal glands.

**Use in elderly**

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

### How to take it

#### How much to take

Your doctor will tell you how much Panafcortelone to take.

The dose will depend on the condition being treated and your response to the treatment. Your initial dose will be maintained or adjusted until a satisfactory response is noted.

#### How to take it

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

#### When to take it

Panafcortelone is best taken with or immediately after food.

How often Panafcortelone can be taken may vary depending on what condition is being treated. It can be taken once daily, several times a day or on alternate days (every other day).

If you take it once a day or every second day, then it is best taken at breakfast time. If it needs to be taken more than once a day, then space it out during the day.

#### How long to take it

**Continue taking Panafcortelone for as long as your doctor tells you.**

This will depend on your condition and on your response to treatment. Some people will need this medicine for only short periods of time whilst others may require long term therapy.

**Do not miss any doses and do not stop taking the medicine even if you feel better.**

Missing doses may make your symptoms worse.

#### What to expect

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

#### 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 you take Panafcortelone.

If you are taking Panafcortelone:

- once a day-  
If you miss a dose and remember in less than 12 hours, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

- several times a day-  
If you miss a dose and it is more than 2 hours before your next dose is due, take it straight away and then continue as you normally would.  
If it is less than 2 hours to your next dose, skip the dose you have missed but be sure to take the next dose when you are meant to.
- 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 try to make up for missed doses by taking more than one dose at a time.**

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

*If you take too much (overdose)*

**Immediately telephone your doctor or 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 Panafcortelone. 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 Panafcortelone exactly as your doctor has prescribed.**

If you do not follow your doctor's instructions 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 becomes worse after your dose of Panafcortelone has been reduced or treatment has been stopped.**

**Tell your doctor immediately if you become pregnant while taking Panafcortelone.**

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking Panafcortelone, especially if you are being started on any new medicines.**

**Tell your doctor, surgeon or dentist that you are taking Panafcortelone if you are about to undergo surgery or an operation.**

Your dose of this medicine may need to be increased to cover you during the stress of the operation.

**Tell your doctor straight away if you are a diabetic, and you notice a change in the results of your blood or urine sugar tests.**

This medicine 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 Panafcortelone.

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

If you have been taking it for a long time your doctor may gradually reduce the amount you are taking over a period of several days, weeks or months before stopping completely.

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

*Things you must not do*

**Do not give this medicine to anyone else even if their symptoms seem similar to yours.**

**Do not stop taking Panafcortelone suddenly unless advised by your doctor.**

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

**Do not have any immunisations (particularly with "live" vaccines such as measles, oral polio or yellow fever) without your doctor's approval while you are being treated with Panafcortelone.**

*Things to be careful of*

**Avoid close contact with anyone who has a contagious disease such as measles or chickenpox.**

Exposure to such diseases while you are taking this medicine, particularly if large doses are being taken, can put you at greater risk of developing these diseases if you have not had them before.

**Tell your doctor straight away if you think you have been exposed to chickenpox or measles.**

*Things to be aware of*

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

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

If you drink alcohol while taking it you may find that stomach problems occur.

The signs and symptoms of infections such as fever or inflammation may be hidden by the anti-inflammatory action of Panafcortelone. You should see your doctor for medical advice for any but the most minor infections.

**Side effects**

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

Panafcortelone helps most people who take it, but it may have unwanted side effects in some people. 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 side effects.

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

*Short term use*

When Panafcortelone is taken for short periods of time it is unlikely to cause any problems.

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

- mood changes
- nausea (feeling sick)
- vomiting
- anorexia (which may result in weight loss)
- increased appetite (which may result in weight gain)
- stomach bloating or irritation
- diarrhoea or constipation.

*Long term use*

When Panafcortelone 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 the body:**

- bloating and rounding of the face (moon face)
- headache
- dizziness
- weight gain
- redistribution of body fat
- water retention leading to swollen legs and feet, high blood pressure or an irregular heart beat
- cramps or weakness in the muscles of the arms and legs
- slowed growth in children
- irregular menstrual periods.

**changes to the skin:**

- acne
- red or flushed face
- extra hair growth
- red or purple streaks
- easy bruising
- skin thinning
- increased sweating
- poor wound healing.

**changes to the immune system:**

- an increased seriousness or frequency of infections.

**changes in behaviour:**

- excessive mood swings (such as changes in personality)
- anxiety or nervousness
- restlessness
- trouble sleeping.

**changes in eyes:**

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

**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
- epileptic fits
- sudden changes to your vision
- symptoms such as severe dizziness, fainting, weakness, chest pain or irregular heart beat
- psychiatric disturbances.

These are all serious side effects of Panafcortelone. You may need urgent medical attention or hospitalisation.

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

Such side effects may include:

- osteoporosis or other changes in bone which can result in an increased chance of fractures due to brittleness or softening of the bone
- changes in other hormone levels in your body
- changes in the body's ability to handle glucose (steroid diabetes)
- effects on the parathyroid and thyroid glands which control calcium and body metabolism
- increased amounts of cholesterol in the blood
- changes to your white blood cells

- changes to your nervous system which may affect the way your nerves work
- changed sperm count
- increased blood pressure
- increased pressure in the skull.

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

Some people may get other side effects while using Panafcortelone.

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

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#### After taking it

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##### *Storage*

**Keep Panafcortelone tablets in a cool dry place, protected from light, where the temperature stays below 30°Celsius.**

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

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 ground is a good place to store medicines.

##### *Disposal*

**Dispose of the tablets where children cannot reach them.**

**If your doctor tells you to stop taking Panafcortelone, or you find that the expiry date has passed, ask your pharmacist what to do with any tablets you may have left over.**

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#### Product description

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##### *What it looks like*

Panafcortelone tablets are available in three strengths: 1 mg, 5 mg and 25 mg.

- The 1 mg tablets are white, scored, round and flat. They are marked with "PL/1" on one side. Available in bottles of 100 tablets.
- The 5 mg tablets are white, scored, round and flat. They are marked with "PL/5" on one side. Available in bottles of 60 tablets.
- The 25 mg tablets are white, scored, round and biconvex. They are marked with "PL/25" on one side. Available in bottles of 30 tablets.

##### *Ingredients*

###### **Active ingredient:**

- Panafcortelone 1 mg - 1 mg prednisolone per tablet
- Panafcortelone 5 mg - 5 mg prednisolone per tablet
- Panafcortelone 25 mg - 25 mg prednisolone per tablet.

###### **Inactive ingredients:**

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

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

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#### Sponsor

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

#### **Australian Registration Numbers:**

1 mg tablets: AUST R 27960

5 mg tablets: AUST R 27962

25 mg tablets: AUST R 27964

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