

SCHEDULING STATUS: **S4**

PANAFECORT 5 mg TABLETS

Prednisone

Contains sugar (lactose): 50,2 mg per tablet

Read all of this leaflet carefully before you start taking PANAFECORT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PANAFECORT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PANAFECORT is and what it is used for
2. What you need to know before you take PANAFECORT
3. How to take PANAFECORT
4. Possible side effects
5. How to store PANAFECORT
6. Contents of the pack and other information

1. What PANAFECORT is and what it is used for

PANAFECORT contains prednisone which belongs to a group of medicines called corticosteroids.

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It is used to provide relief from symptoms of inflammation that may be caused by a range of inflammatory diseases, including:

- rheumatism (inflammation of joints and connective tissue);
- allergic reactions and allergic conditions;
- skin diseases.

2. What you need to know before you take PANAFECORT

Do not take PANAFECORT:

- if you are hypersensitive (allergic) to prednisone or any of the other ingredients of PANAFECORT (listed in section 6).
- if you have a stomach ulcer or an ulcer of the small intestines (gut).
- if you have osteoporosis (bones become less dense over time, weaker, more brittle and more likely to break).
- if you have mental health problems for example severe anxiety or nervousness, or if you suffer from psychosis (where you have lost some degree of contact with reality and / or is seeing, hearing, and/or believing things that aren't real).
- if you currently have a fungal, bacterial or viral infection or you get an infection while being treated with PANAFECORT, unless advised by your doctor.
- if you recently had a vaccination, like for example against smallpox.
- if you have liver problems.

Warnings and precautions

Take special care with PANAFECORT:

- Immunisation procedures should not be undertaken in patients taking corticosteroids, like PANAFECORT

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- if you have heart failure.
- if you have diabetes or if you are diabetic and taking insulin to control your blood sugar levels.
- if you have kidney disease (chronic renal failure or uraemia).
- if you are elderly.
- if you are taking diuretics (water tablets), that can cause low potassium levels (diuretics can be used in the treatment of high blood pressure or heart failure).
- if you use PANAFECORT over a prolonged period of time as your kidneys may not be able to filter waste from the blood
- if you use PANAFECORT in large doses you may have moon-face (filling or rounding out of the face) sometimes with hirsutism (excessive hair growth or abnormal hair distribution), buffalo hump (increased amount of fat in the upper back and neck, making a “hump”), flushing, increased bruising, acne and striae (reddish purple lines on arms, face, groin, legs or trunk).
- if you reduce the dose suddenly during the treatment of rheumatoid arthritis, fatalities due to damage of arteries can occur, an increase in blood clotting ability (coagulation) may lead to obstruction of blood vessel (thromboembolism)
- if you use PANAFECORT, it may cause a reduction of circulating white blood cells if you have excessive metabolic effects, this could lead to mobilisation of calcium and phosphorus causing osteoporosis (bones to become brittle and fragile due to loss of tissue) and spontaneous fractures as well as depletion of nitrogen
- if you have tuberculosis (also known as TB) or a history of tuberculosis (a type of infection, usually of the lungs).
- if you are scheduled to go for an operation. Tell your doctor you are taking PANAFECORT, even if you have stopped taking PANAFECORT, before you go for surgery / an operation.

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- if you have an infection or develop an infection while taking PANAFKORT. While taking PANAFKORT you can get infections more easily than usual and if you have an infection, the symptoms may be masked (covered up). Tell your doctor if you feel feverish as this may be a sign of a new infection or an existing infection may be worse.
- if you are currently taking antibiotics, used to treat bacterial infections. Taking antibiotics at the same time as PANAFKORT can increase the chance of a secondary infection (i.e., another infection in a different location), like oral thrush.
- if you have inflammatory diseases of the bowel (ulcerative colitis) and your doctor has told you that you are at risk of perforation (rupture) in the colon or inflammation of the abdominal lining (known as peritonitis).
- if you are taking a high dose of PANAFKORT because you may experience a slower heart rate than normal (known as bradycardia).
- if you have pheochromocytoma (a tumour / cancer of the adrenal gland).
- if you use PANAFKORT, it may increase your insulin requirements and your doctor may need to adjust your insulin dose accordingly.

If any of the above applies to you, or if you are unsure, talk to your doctor or pharmacist before taking PANAFKORT.

Other medicines and PANAFKORT

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Vaccinations

Before taking PANAFKORT, tell your doctor if you have been vaccinated recently. If you are going to have any vaccinations, tell your doctor, pharmacist or nurse that you are taking PANAFKORT.

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Some vaccines should not be given to patients taking PANAFECORT because prednisone (the active substance) can affect the way some vaccines work (see section 2: “Do not take PANAFECORT”).

It is especially important that your doctor knows if you are taking any of the following medicines:

- medicines that can reduce the effects of PANAFECORT:
 - barbiturates (sedatives).
 - phenylbutazone (an anti-inflammatory medicine used to treat pain and inflammation).
 - phenytoin (used to treat epilepsy / fits).
 - rifampicin (used for treatment of tuberculosis).
- anti-coagulant medicines, which prevent blood clots (also known as blood thinners), for example warfarin. PANAFECORT may change your body's response to anti-clotting medicines and your doctor is likely to monitor you more closely.
- some diuretics (also known as water tablets), specifically those that decrease potassium blood levels, such as hydrochlorothiazide or furosemide.
- insulin. PANAFECORT may increase your insulin requirements and your doctor may need to adjust your insulin dose accordingly.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Taking PANAFECORT while you are pregnant can affect your newly born baby.

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Corticosteroids, like PANAFECORT, pass into breast milk and mothers receiving corticosteroids should be advised not to breastfeed.

Driving and using machines

It is not always possible to predict to what extent PANAFECORT may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which PANAFECORT affects you.

PANAFECORT contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PANAFECORT.

PANAFECORT contains sodium

PANAFECORT contains less than 1 mmol sodium (23 mg) per tablet; that is to say it is essentially 'sodium-free'.

3. How to take PANAFECORT

Do not share medicines prescribed for you with any other person.

Always take PANAFECORT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 2 to 20 tablets daily, taken in divided doses.

- Your doctor will tell you how many tablets to take and for how long you should take PANAFECORT.
- Your dose will depend on the severity of your symptoms and on your response to treatment.
- PANAFECORT must be taken with or after food.

Your doctor will tell you how long your treatment with PANAFECORT will last. Do not stop treatment

early because this may result in undesirable side effects.

If you have the impression that the effect of PANAFECORT is too strong or too weak, tell your doctor or pharmacist

If you take more PANAFECORT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PANAFECORT

If you forget a dose, take it as soon as you remember. However, if it is almost time for your next dose, *do not* take the missed dose and take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking PANAFECORT

Do not stop taking PANAFECORT without talking to your doctor because you may need to reduce the dose slowly over time.

If treatment is stopped too quickly it can lead to serious problems of the adrenal gland. You may also experience 'withdrawal symptoms' which include fever, muscle and joint pain, runny nose, an eye infection (conjunctivitis), painful itchy skin lumps, weight loss, feeling sick and/or being sick, low blood pressure, feeling faint, headache, blurred vision, dizziness and reappearance of your disease symptoms.

4. Possible side effects

PANAFECORT can have side effects.

Not all side effects reported for PANAFECORT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PANAFECORT, please consult your health care provider for advice.

If any of the following happens, stop taking PANAFECORT and tell your doctor immediately or go to the casualty department at your nearest hospital:

you pass black tarry stools or notice fresh or clotted blood in your stools (faeces). You may also notice dark bits that look like coffee grounds in your vomit. These could be signs of a stomach ulcer with bleeding.

- severe abdominal (stomach) pain, feeling cold (chills), fever, feeling sick (nausea) or being sick (vomiting). These could be signs of gastrointestinal perforation (also known as ruptured bowel) which is a hole in the wall of a part the gut.
- symptoms of blood clots lodging, causing either:
 - heart attack (symptoms include chest pain or pain below your breastbone; discomfort, pressure, heaviness or tightness in your chest; pain or discomfort that spreads to the shoulder, arm, back, neck, jaw, teeth or sometimes the upper belly; nausea; dizziness; shortness of breath);
 - stroke (symptoms include numbness of the face, arm or leg; trouble speaking or understanding what others are saying; trouble walking; headache; blurred or blackened vision or seeing double);
 - pulmonary embolism (lung clot) or deep vein thrombosis (clot in the leg) causing shortness of breath, chest pain, cough, rapid or irregular heartbeat, feeling lightheaded (dizzy), excessive sweating, clammy or bluish discoloured skin, leg pain or swelling (or both), usually in the calf.

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- slow heart rate, chest pain or discomfort, shortness of breath, pounding feeling in your chest, dizziness or fainting, swelling in the legs or feet, or heart palpitations (feeling of skipped heartbeats, fluttering or your heart “running away”). These may be signs and symptoms of heart problems like bradycardia (slow heart rate), irregular heartbeats or heart failure (where the heart is not pumping correctly).
 - severe headaches, nausea and vomiting and loss of vision. These may be signs of increased pressure in the brain known as benign intra-cranial hypertension.
 - signs of “withdrawal” after you have stopped taking PANAFECORT (see section 3: “If you stop taking PANAFECORT”).

These are all very serious side effects. If you have them, you may have had a serious side effect from PANAFECORT. You may need urgent medical attention or hospitalisation.

Tell your doctor straight away if you notice any of the following side effects:

Signs or symptoms of serious mental health problems, for example:

- feeling severely depressed, including thinking about suicide.
- feeling severely irritable or anxious.
- feeling, seeing and hearing things that are not real.
- loss of touch with reality.
- changes in how you feel or act.

Steroids like, and including, PANAFECORT, can cause serious mental health problems.

Wound healing and infection:

- a very sore throat, sudden onset of fever, low body temperature, shaking, chills, confusion or difficulty breathing. These may be signs that your body is fighting an infection, which may be serious and severe. You may also have difficulty in swallowing and the inside of your mouth may have white spots. Remember that you can get infections more easily than usual while taking PANAFECORT and that the signs and symptoms of infection may be

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masked.

- delayed (slow) or improper wound healing (wounds and cuts that do not heal as quickly as usual or not as well as it should).
- increase likelihood of infection of the wound.

If you notice any of the above problems talk to a doctor as soon as possible.

Other side effects, for which the frequency is not known:

- moon-face (filling or rounding out of the face) sometimes with hirsutism (excessive hair growth or abnormal hair distribution), buffalo hump (increased amount of fat in the upper back and neck, making a “hump”), flushing, increased bruising, acne and striae (reddish purple lines on arms, face, groin, legs or trunk).
- changes in the electrolyte (salt) balance.
- sodium and water retention with swelling.
- low levels of potassium in the blood, which may result in tiredness, confusion or muscle cramps.
- osteoporosis (where the bones become less dense over time, weaker and more brittle, and subsequently more likely to break).
- spontaneous fractures (breaks in your bones).
- increase in blood sugar levels which may cause (or worsen) diabetes.
- increase in insulin requirements in persons with diabetes.
- increased appetite.
- increase in blood pressure.
- absence of period (monthly menstrual period).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under

SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PANAFECORT.

5. How to store PANAFECORT

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in the original container.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PANAFECORT contains

- The active substance is prednisone. Each tablet contains 5 mg prednisone.
- The other ingredients are maize starch, lactose, sodium starch glycolate, sodium lauryl sulphate and magnesium stearate.

What PANAFECORT looks like and contents of the pack

PANAFECORT are white, round, normal, convex tablets.

PANAFECORT tablets can be packed into the following pack types:

- 1000's packed into white polypropylene securitainers with a white LDPE snap-on cap or round amber glass bottle with a polypropylene screw-cap.
- 5000's packed into 1 L white HDPE bucket with handles, with HDPE closures.
- 100's and 500's packed into polypropylene securitainers with LDPE closures.

Holder of Certificate of Registration

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