

**SCHEDULING STATUS:** **S4**

**PANAFKORT 5 mg TABLETS**  
**Prednisone**  
**Contains sugar (lactose): 50,2 mg per tablet**

**Read all of this leaflet carefully before you start taking PANAFKORT.**

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

**1. What PANAFKORT is and what it is used for**

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

**Do not take PANAFKORT:**

- if you are hypersensitive (allergic) to prednisone or any of the other ingredients of PANAFKORT (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 PANAFKORT, unless advised by your doctor.

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- if you recently had a vaccination, like for example against smallpox.
- if you have liver problems.

### Warnings and precautions

Take special care with PANAFKORT:

- if you need to be vaccinated, as certain vaccines should not be administered during certain treatments with PANAFKORT, you should wait 3 months after stopping treatment with PANAFKORT before being vaccinated.
- 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 PANAFKORT over a prolonged period of time as your kidneys may not be able to filter waste from the blood.
- if you use PANAFKORT 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 PANAFKORT, 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 PANAFKORT, even if you have stopped taking PANAFKORT, before you go for surgery / an operation.
- 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

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abdominal lining (known as peritonitis).

- 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 you have liver problems.
- if you have menopause or have gone through menopause. The effect of PANAFKORT may be reduced if you have one of these conditions.
- if you have ever had depression or manic-depression. This includes having had depression before or whilst taking steroid medicines such as PANAFKORT or if any of your close family members have had these illnesses. Mental health problems, which can be serious, can occur while taking PANAFKORT and treatment for this may be needed. If you (or someone taking this medicine) show any signs of mental health problems, talk to your (or their) doctor. This is particularly important if you are depressed or might be thinking about suicide.
- Epilepsy and/or seizures, as in some cases taking PANAFKORT may aggravate your condition.
- if you ever had muscle weakness associated with steroid treatment, as PANAFKORT may result in further muscle weakness.
- if you have a condition known as myasthenia gravis (a neuromuscular disorder that causes weakness in the skeletal muscles, which are the muscles your body uses for movement). The medicine you use to control the myasthenia gravis may not work as well if you are also taking PANAFKORT.
- if you have blood clotting (thromboembolic) disorders.
- if you are taking a high dose of PANAFKORT you may experience a slower heart rate than normal (known as bradycardia). This can also happen at lower doses of PANAFKORT and especially if you have heart or kidney problems, if you are taking other medicine that slows down heart rate or if you have a salt (electrolyte) imbalance (which can be caused by water pills, also known as diuretics, or from excessive vomiting). Your doctor may advise you to stop taking PANAFKORT.
- if you develop calciphylaxis (a serious, uncommon disease in which calcium accumulates in small blood vessels of the fat and skin tissues). Calciphylaxis causes blood clots, painful skin ulcers and may cause serious infections that can lead to death. Patients who have calciphylaxis usually have kidney failure and are on dialysis or have had a kidney transplant. The condition can also occur in patients without kidney disease.
- if you suddenly stop treatment, increase, or reduce your dose of PANAFKORT, this may cause acute adrenal insufficiency (you may experience muscle and joint pain, shortness of breath, nausea and vomiting, fever, low blood pressure, dehydration) requiring prompt, emergency medical treatment.
- if PANAFKORT has been prescribed to you, you should take care not to come into contact with someone who has chickenpox or measles. Seek immediate medical advice if you are exposed to either chickenpox or measles.

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- if you experience problems with your eyes or eyesight (vision), including blurred vision, while taking PANAFKORT. You may need to be referred to an ophthalmologist (eye specialist).
- if you have Cushing's disease (a condition in which there is too much cortisol hormone in the body). Common symptoms include upper body obesity, severe fatigue, high blood pressure, backache, elevated blood sugar, easy bruising, and bluish-red stretch marks on the skin.
- if you stop taking PANAFKORT, this could result in raised intracranial pressure which may cause headaches, blurred vision, vomiting, changes in your behaviour, weakness, or problems with moving or talking, feeling less alert than normal, lack of energy or sleepiness
- if you have scleroderma (also known as systemic sclerosis, an autoimmune disorder). Daily doses of 15 mg or more of PANAFKORT may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and passing less urine. Your doctor may tell you that you should get your blood pressure and urine checked regularly.
- if you are elderly. If you are elderly, your doctor will monitor you closely while taking PANAFKORT as you may be more likely to experience side effects, like high blood pressure, diabetes, increased risk of infections and thinning of the skin.

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

Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your health care provider will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

### **Children and adolescents**

If the patient is a child, it is important that the doctor monitors growth and development at intervals during treatment.

### **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.

Some vaccines should not be given to patients taking PANAFKORT because prednisone (the

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active substance) can affect the way some vaccines work (see *section 2: "Do not take PANAFKORT"*).

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

- medicines that can reduce the effects of PANAFKORT:
  - barbiturates (sedatives).
  - phenylbutazone (an anti-inflammatory medicine used to treat pain and inflammation).
  - carbamazepine, phenobarbital, phenytoin and primidone (used to treat epilepsy / fits).
  - rifampicin (used for treatment of tuberculosis).
  - antacids, that are used to neutralise stomach acidity and is used to relieve heartburn, indigestion, or an upset stomach.
  - antibiotics (such as erythromycin).
  - antithyroid medicines such as carbimazole.
  - mifepristone (a medicine used to terminate pregnancy). Mifepristone will reduce the effects of PANAFKORT for 3 to 4 days after taking it.
- medicines that can increase the effects of PANAFKORT:
  - ritonavir, indinavir or other antiviral medicines used to treat HIV.
  - ciclosporin (used to prevent rejection after organ transplant and in the treatment of rheumatoid arthritis).
  - female sex hormones (oestrogens) taken together with PANAFKORT may require dosage adjustments.
- hypokalaemia (low level of potassium in the blood) may result when PANAFKORT is used together with the following medicines:
  - some diuretics (also known as water tablets), specifically those that decrease potassium blood levels, such as hydrochlorothiazide or furosemide.
  - medicines used in the treatment of asthma (or other conditions due to breathing difficulties) like bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline, as they may result in an increased risk of hypokalaemia (low potassium levels) if taken with high doses.
  - antifungal medicines such as amphotericin, which may increase the risk of hypokalaemia (low potassium levels), and ketoconazole.
  - carbenoxolone, used in the treatment of stomach ulcers.
  - acetazolamide, used in the treatment of glaucoma and epilepsy.
- isoniazid, used for the treatment of tuberculosis (TB). Your doctor may need to adjust your isoniazid dosage.
- anti-coagulant medicines, which prevent blood clots (also known as blood thinners), for example warfarin. PANAFKORT may change your body's response to anti-clotting medicines and your doctor is likely to monitor you more closely.
- insulin. PANAFKORT may increase your insulin requirements and your doctor may need to adjust your insulin dose accordingly.

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- antimuscarinics medicines used to treat conditions such as myasthenia gravis (weakness and rapid fatigue of the muscles under your voluntary control), if taken with PANAFKORT may cause memory impairment if you are elderly.
- digoxin, used in the treatment of heart conditions. If low blood potassium levels occur, due to PANAFKORT, the chances of serious undesirable effects from digoxin are increased.
- methotrexate, a medicine used for rheumatoid arthritis, psoriasis, and certain types of cancer. If taken together with PANAFKORT, it may result in serious undesirable effects of the blood cells, possibly causing infection, bleeding, or anaemia.
- oral contraceptives may increase the blood level of PANAFKORT resulting in an increased chance of undesirable effects.
- immunosuppressants, medicines which dampen down the activity of the body's immune system.
- anti-inflammatory medicines like salicylates, aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs), like diclofenac and ibuprofen, used for treating inflammation and pain. When taken together with PANAFKORT, your risk of severe stomach problems increases, along with an increased chance of undesirable effects.
- somatropin (growth hormone) because the growth promoting effect may be stopped if used with PANAFKORT.

### **PANAFKORT with food**

Avoid eating liquorice whilst taking PANAFKORT.

### **Pregnancy, breastfeeding, and fertility**

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 PANAFKORT while you are pregnant can affect your newly born baby. Cataracts and low birth weight have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

Small amounts of PANAFKORT may get into your breast milk. This may suppress growth and harm your baby.

PANAFKORT may cause missed or irregular menstruation.

### **Driving and using machines**

PANAFKORT may make you feel tired, dizzy or may affect your vision after treatment. If you are affected do not drive or operate any tools or machinery.

It is not always possible to predict to what extent PANAFKORT 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 PANAFKORT affects you.

**PANAFKORT contains lactose**

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

**PANAFKORT contains sodium**

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

**3. How to take PANAFKORT**

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

Always take PANAFKORT 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 PANAFKORT.
- Your dose will depend on the severity of your symptoms and on your response to treatment.
- PANAFKORT must be taken with or after food.

Your doctor will tell you how long your treatment with PANAFKORT will last. Do not stop treatment early because this may result in undesirable side effects.

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

**If you take more PANAFKORT 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 PANAFKORT**

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 PANAFKORT**

Do not stop taking PANAFKORT 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,

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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**

PANAFKORT can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 areas on the surface. Remember that your sensitivity to all kinds of infection may be increased and PANAFKORT may mask the signs and symptoms of infection.
- coughing for a few weeks, coughing up blood or mucous, unintentional weight gain, tiredness, night sweats (tuberculosis).
- fits (convulsions). If you have epilepsy, you may notice you get fits (seizures) more often than usual or they are more severe.
- 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.
- severe upper stomach pain with nausea or vomiting. These may be signs of a problem with your pancreas (inflammation of the pancreas).
- ongoing pain in any joint, as this might be a sign of osteonecrosis (death of bone tissue). Initially, you may not have any symptoms due to osteonecrosis; however, as the condition worsens, affected joints might hurt only when putting weight on them. Eventually, you might feel the pain even when you're lying down. The pain can be mild or severe.
- sudden high blood pressure, kidney failure and decreased urine production, particularly

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- if you have sclerosis (scleroderma renal crisis).
- 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.
  - 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).
  - deep, very painful lumps that develop into open sores that do not heal, purple net-like patterns on the skin (calciophylaxis).
  - 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 PANAFKORT (see section 3: “If you stop taking PANAFKORT”).

These are all very serious side effects. If you have them, you may have had a serious side effect from PANAFKORT. 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 high (mania) or an exaggerated state of happiness (euphoria).
- moods that go up and down.
- feeling severely irritable or anxious.
- loss of memory.
- difficulty in thinking or being confused.
- having problems sleeping (insomnia).
- feeling, seeing and hearing things that are not real (or if you suffer from schizophrenia the condition may worsen).
- loss of touch with reality.
- changes in how you feel or act.

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

*Wound healing and infection:*

- delayed (slow) or improper wound healing (wounds and cuts that do not heal as quickly

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as usual or not as well as it should).

- increase likelihood of infection of the wound.

### *Eye problems*

- changes in your vision (how you see) like sudden appearance of many floaters or blurred vision or bulging (protruding) of the eyes. These may be signs of eye problems such as glaucoma (increased eye pressure), cataracts (clouding of the lens of the eyes) or other serious eye problems.

### 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).
- dry mouth, difficulty swallowing, white lesions in your food pipe (candidiasis).
- fever, bleeding, bruising, sweating, loss of weight without trying (leucocytosis).
- 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 weight.
- high levels of bad cholesterol in the blood.
- increased sweating.
- increase in blood pressure.
- thin delicate skin, unusual marks on the skin or bruising, appearance of stretch marks, acne, rash, itching and hives.
- muscle pain or weakness in upper or lower limbs.
- bone problems such as fragile bones or wasting of the bones (osteoporosis).
- breaks in your bones (fractures).
- tendon rupture (when a muscle is torn from the bone at the point of attachment), particularly of the ankle and knee tendons.
- menstrual (period) irregularities such as excessive, delayed or absence of period (amenorrhoea).
- trouble falling and/or staying asleep (insomnia), dizziness, headache.
- worsening of eye infections (viral or fungal).
- vertigo causing a spinning sensation or a feeling of being unbalanced with or without nausea and ringing in ears (or hearing loss).
- feeling sick (nausea), stomach pain, diarrhoea.
- general feeling of being unwell.

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- growth retardation in children.

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

### 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PANAFKORT.

You may also report to Adcock Ingram Limited using the following e-mail address: Adcock.AEReports@adcock.com.

### 5. How to store PANAFKORT

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 PANAFKORT 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 PANAFKORT looks like and contents of the pack

PANAFKORT are white, round, normal, convex tablets.

PANAFKORT 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

Adcock Ingram Limited

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