SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

PANAFCORT 5 mg TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Prednisone	5 mg
Contains sugar: Lactose	50,2 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

White, round, normal,convex tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Severe or acute rheumatic, dermatological and allergic conditions, collagen diseases, musculoskeletal conditions.

4.2 Posology and method of administration

Posology

Take with or after food, 2 to 20 tablets daily in divided doses

Method of administration

Oral.

4.3 Contraindications

- Known hypersensitivity to prednisone or to any of the excipients listed in section 6.1.
- Peptic ulcer.
- Osteoporosis.
- Psychosis or severe psychoneuroses.
- Presence of acute bacterial infections, herpes zoster, herpes simplex, ulceration of the eye and other viral infections.
- Vaccination against smallpox and other infections.
- Liver disease.

4.4 Special warnings and precautions for use

- Immunisation procedures should not be undertaken in patients taking corticosteroids, like PANAFCORT (see section 4.3).
- Use with caution in the presence of congestive heart failure, diabetes mellitus, infectious diseases, chronic renal failure and uraemia and in elderly persons.
- Acute adrenal insufficiency may occur during prolonged treatment or on cessation of treatment and may be precipitated by an infection or trauma.
- Large doses may produce symptoms typical of hyperactivity of the adrenal cortex, with moon-face, sometimes with hirsutism, buffalo hump, flushing, increased bruising, striae and acne, sometimes leading to a fully developed Cushing's syndrome.
- On sudden reduction of dosage during the treatment of rheumatoid arthritis, fatalities have been attributed to lesions of small arteries and arterioles similar to polyarteritis, an increase in blood coagulability may lead to thromboembolic complications.
- The administration of prednisone may also cause a reduction in the number of circulating lymphocytes.
- Disturbance of electrolyte balance manifests with retention of sodium and water, oedema, hypertension and increased excretion of potassium with the possibility of hypokalaemic alkalosis.

In extreme cases, cardiac failure may be induced.

- Excessive metabolic effects lead to mobilisation of calcium and phosphorus with osteoporosis and spontaneous fractures, nitrogen depletion.
- The insulin requirements of diabetic patients are increased.
- Patients concurrently taking diuretics which cause potassium depletion should be watched carefully for signs of hypokalaemia.
- Patients with active or doubtfully quiescent tuberculosis should not be given these hormones except as adjuncts to treatment with tuberculostatic medicines. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.
- There is normally an increased secretion of corticosteroids by the adrenals in response to infection or stress caused by anaesthesia, surgery or trauma; patients receiving corticosteroids, like PANAFCORT, or who have been given corticosteroids in the previous 3 months may have insufficient adrenal reserve and should be given supplementary corticosteroids.
- Hyperglycaemia with accentuation or precipitation of the diabetic state have been reported. The insulin requirements of diabetic patients are increased. Increased appetite is often reported.
- Increased susceptibility to all kinds of infection has been reported, including sepsis, fungous infections and viral infections, e.g., *Candida* infection of the mouth especially if given concomitantly with antibiotics.
- Infections may be masked since steroids, like PANAFCORT, have marked anti-inflammatory properties with analgesic and antipyretic effects and may produce a feeling of well-being.
- Caution must be observed in ulcerative colitis if a possibility exists of intestinal perforation and peritonitis.
- Bradycardia has been reported following high doses.
- Pheochromocytoma crisis, which can be fatal, has been reported after administration of systemic corticosteroids, like PANAFCORT. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Excipients

PANAFCORT contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

4.5 Interaction with other medicines and other forms of interaction

Concurrent administration of barbiturates, phenylbutazone, phenytoin or rifampicin may enhance the metabolism and reduce the effects of prednisone, as contained in PANAFCORT.

Response to anticoagulants may also be reduced by corticosteroids, like PANAFCORT.

Patients concurrently taking diuretics which cause potassium depletion should be watched carefully for signs of hypokalaemia.

4.6 Fertility, pregnancy and lactation

Babies born of mothers who received large doses corticosteroids, like PANAFCORT, during pregnancy should be watched carefully for signs of hypoadrenalism.

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

4.7 Effects on ability to drive and use machines

The effect on the ability to drive or use machinery has not been evaluated. There is no evidence to suggest that PANAFCORT may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgement and/or sound coordination and vision.

4.8 Undesirable effects

Tabulated summary of adverse reactionss

System Organ Class	**Frequent**	**Less frequent**	**Frequency not known**
Infection and			Increased susceptibility to infection, infections may be

infestations			masked (see section 4.4).
Blood and lymphatic system disorders			Increase in blood coagulability leading to thromboembolic complications, decreased circulating lymphocytes
Endocrine disorders			Adrenal cortex hyperactivity, Cushing's syndrome, acute adrenal insufficiency.
Metabolism and nutrition disorders			Disturbance of electrolyte balance, sodium and water retention, oedema, increased excretion of potassium with the possibility of hypokalaemic alkalosis, mobilisation of calcium and phosphorus with osteoporosis and spontaneous fractures, nitrogen depletion, hyperglycaemia with accentuation or precipitation of the diabetic state, increased insulin requirements of diabetic patients, increased appetite (see section 4.4).
Psychiatric disorders			Mental disturbances.
Nervous system disorders			Neurological disturbances.
Cardiac disorders			Bradycardia, cardiac failure may be induced (see section 4.4).
Vascular disorders			Hypertension, intracranial hypertension, lesions of small arteries and arterioles.
Gastrointestinal disorders			Peptic ulceration with haemorrhage and perforation.
Reproductive system and breast disorders			Amenorrhoea.

General disorders and administrative site conditions			An effect on tissue repair (delayed wound healing, increased liability to infection).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Reports of acute toxicity and/or death following overdosage of glucocorticoids, like PANAFCORT, are infrequent.

See section 4.8 for possible signs and symptoms of overdose.

High systemic doses of corticosteroids, like PANAFCORT, caused by chronic use have been associated with adverse effects such as neuropsychiatric disorders (psychosis, depression and hallucinations), cardiac dysrhythmias and Cushing's syndrome.

No specific antidote is available. Treatment is supportive and symptomatic. Serum electrolytes should be monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological Classification: A 21.5.1 Corticosteroids and analogues.

Pharmacotherapeutic group: Corticosteroids for systemic use.

ATC code: H02AB06.

Prednisone is a synthetic glucocorticoid. It has anti-inflammatory actions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

Lactose

Sodium starch glycolate

Sodium lauryl sulphate

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years: Securitainers of 1000’s

2 years: Securitainers of 100, 500’s and 5000’s in a white HDPE bucket

6.4 Special precautions for storage

Store in airtight container at or below 25 °C and protect from light.

6.5 Nature and contents of container

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.

Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER(S)

G3054 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

December 1974

10. DATE OF REVISION OF THE TEXT

09 May 2023

Namibia (NS2) : 14/21.5.1/0405
Botswana (S2): B9323895
Zimbabwe: [PP] 2004/17.1/4274

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