Patient Information Leaflet

SCHEDULING STATUS S4

BE-TABS PREDNISONE 5 mg TABLETS

Prednisone

Contains sugar (lactose monohydrate): 106 mg per tablet

Read all of this leaflet carefully before you start taking BE-TABS PREDNISONE 5 mg

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

1. What BE-TABS PREDNISONE 5 mg is and what it is used for

BE-TABS PREDNISONE 5 mg contains prednisone. Prednisone belongs to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as prednisone) is an effective way to treat various illnesses involving inflammation in the body. Prednisolone reduces this inflammation, which could otherwise go on making your condition worse.

BE-TABS PREDNISONE 5 mg are used in a wide range of inflammatory and auto-immune conditions including:

- inflammation of joints (rheumatoid arthritis)
- kidney disease (nephrotic syndrome)
- "auto-immune" diseases called collagen diseases (where your body fights against itself)
- a form of life-threatening disease affecting the skin, joints and kidneys (systemic lupus erythematosus)
- allergic reactions that are not controlled by a group of drugs called antihistaminics
- asthma that is not controlled by other measures
- skin diseases
- severely ill patients with long standing inflammatory diseases of the bowel (ulcerative colitis)
- low blood platelet count to decrease the bleeding tendency
- to prevent organ rejection after a transplant.

2. What you need to know before you take BE-TABS PREDNISONE 5 mg

Do not take BE-TABS PREDNISONE 5 mg:

- if you are hypersensitive (allergic) to prednisone or any other ingredients of BE-TABS PREDNISONE 5 mg (listed in section 6)
- if you have liver problems
- if you have a stomach ulcer (symptoms include pain and discomfort (indigestion) which is felt between the navel and the breast bone)
- if you have osteoporosis (disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break)
- if you have mental problem like nervousness, feeling sad or happiness that are not justified by reality (psychoneurosis) or there is loss of contact with reality (psychosis)

Warnings and precautions

Take special care with BE-TABS PREDNISONE 5 mg:

- if you have high blood pressure or heart failure
- if you have diabetes or a history of diabetes
- if you have kidney disease (chronic renal failure or uraemia)
- if you are an elderly person
- if you have infections. The signs of infections may be masked and number of white blood cells (lymphocytes) may be reduced
- if you have tuberculosis (a disease of the lungs) or a history of tuberculosis
- if you have inflammatory diseases of the bowel (ulcerative colitis) with the risk of perforation in the colon and fatal inflammation of abdominal lining (peritonitis)
- if you are planning to receive vaccination.
- if you have an adrenal tumour (pheochromocytoma)

Bradycardia (slow heart rate) may occur at high doses of BE-TABS PREDNISONE 5 mg

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking BE-TABS PREDNISONE 5 mg.

Children and adolescents

Talk to your doctor before giving this medicine to babies, children or adolescents as it may slow their growth.

Other medicines and BE-TABS PREDNISONE 5 mg

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

- barbiturates (used to treat fits)
- phenylbutazone (used to relief pain i.e. NSAIDs)
- phenytoin (used to treat fits)
- rifampicin (used to treat tuberculosis)
- anticoagulants (used to prevent blood clot)
- water pills (diuretics)
- insulin (used to treat diabetes)
- vaccinations.

BE-TABS PREDNISONE 5 mg with food and drink

BE-TABS PREDNISONE 5 mg should be swallowed with water. You can take BE-TABS PREDNISONE 5 mg before or after a meal.

Avoid eating liquorice whilst taking BE-TABS PREDNISONE 5 mg.

Pregnancy, breast-feeding 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.

Driving and using machines

If you feel dizzy or tired after taking BE-TABS PREDNISONE 5 mg do not drive or operate machinery until these effects have worn off.

BE-TABS PREDNISONE 5 mg contains lactose monohydrate:

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

BE-TABS PREDNISONE 5 mg contains sodium:

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

3. How to take BE-TABS PREDNISONE 5 mg

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

Always take BE-TABS PREDNISONE 5 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Your doctor may start your treatment with the lowest dose for a minimum period of time to minimise side effects.
- Your dose will depend on the severity of your symptoms and on your response to treatment. The usual daily dose may be between 5 to 120 mg daily.

- Your doctor will tell you the dose as well as the duration of your treatment.
- Your initial dose will be maintained or adjusted until a satisfactory response is noted.
- You need to take this medicine regularly to get the maximum benefit.
- Do not stop taking this medicine without talking to your doctor

If you have the impression that the effect of BE-TABS PREDNISONE 5 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more BE-TABS PREDNISONE 5 mg 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 BE-TABS PREDNISONE 5 mg

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

If you stop taking BE-TABS PREDNISONE 5 mg

Do not stop taking this medicine without talking to your doctor – you may need to reduce the dose gradually.

Your doctor will decide how to lower the dose gradually depending on how long you have been taking BE-TABS PREDNISONE 5 mg, how you are responding to the treatment, your normal dose and what you are being treated for.

If treatment is stopped too quickly it can lead to severe problems of the adrenal gland. You may also experience 'withdrawal symptoms' which include fever, muscular pain, weakness,

joint pain, runny nose, an eye infection (conjunctivitis), painful itchy skin lumps, loss of weight, mental changes, mood changes, feeling sick and/or being sick, low blood pressure, feeling faint, headache, dizziness and reappearance of your disease symptoms.

Children may also experience swelling of the nerves in the eyes due to increase in pressure in and around the brain. Fits/seizures may also be aggravated.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

BE-TABS PREDNISONE 5 mg can have side effects.

Not all side effects reported for BE-TABS PREDNISONE 5 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BE-TABS PREDNISONE 5 mg, please consult your health care provider for advice.

If any of the following happens, stop taking BE-TABS PREDNISONE 5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- shortness of breath, wheezing or difficulty in breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin
- stomach ulcers with bleeding (which can result in vomiting of blood) and perforation (which can result in severe abdominal pain, feeling of coldness, raised body temperature, feeling of sickness and vomiting)
- blood clots which may result in heart attack or strokes.

These are a very serious side effects. If you have them, you may have had a serious allergic reaction to BE-TABS PREDNISONE 5 mg. 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:

- feeling depressed, including thinking about suicide
- feeling high (mania) or moods that go up and down
- feeling anxious, having problems sleeping, difficulty in thinking or being confused, or losing your memory
- feeling, seeing or hearing things which do not exist

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

<u>Frequency not known:</u>

- water and sodium retention leading to swollen legs and feet, high blood pressure or an irregular heart beat
- osteoporosis which can result in an increase chance of bone fractures due to brittleness or softening of the bone
- increased appetite
- poor wound healing with increased risk of infections
- absence of menstrual periods
- raised blood pressure
- increased pressure in the brain (which can cause headaches, nausea and vomiting)

- a change in the levels of some electrolytes or protein in blood tests (potassium reduction, increased sodium and nitrogen depletion).
- Pheochromocytoma crisis, symptoms may include: anxiety, headache, palpitations, sweating, pale skin

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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 BE-TABS PREDNISONE 5 mg.

5. How to store BE-TABS PREDNISONE 5 mg

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Protect from light.

Store in the original package.

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 BE-TABS PREDNISONE 5 mg contains

- The active ingredient is prednisone.
- The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch and sodium starch glycolate.

What BE-TABS PREDNISONE 5 mg looks like and contents of the pack

BE-TABS PREDNISONE 5 mg: White tablet 6,4 mm in diameter, biconvex with a score mark on one side.

Contents of the pack:

100, 500 and 1000 in a securitainer, 500's and 1000's in a white HDPE bottle and 5000 tablets in a white HDPE jar. Patient ready packs of different pack sizes.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

14 Lautre Road,

Stormill, Ext.1,

Roodepoort, 1724

South Africa

This leaflet was last revised in

23 December 2022

Registration numbers

G 3004 (Act 101 of 1965)

NS2	021001382 (Namibia)
Botswana List No.: B9315040	