1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BETANOID SYRUP 0,60 mg /5 ml

Betamethasone

Contains sugar: Glucose 1,5 g and sucrose 0,625 g

Read all of this leaflet carefully before you start taking BETANOID SYRUP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- BETANOID SYRUP 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 BETANOID SYRUP is and what it is used for
2. What you need to know before you take BETANOID SYRUP
3. How to take BETANOID SYRUP
4. Possible side effects
5. How to store BETANOID SYRUP
6. Contents of the pack and other information

1. What BETANOID SYRUP is and what it is used for

BETANOID SYRUP contains the active substance called betamethasone.

BETANOID SYRUP belongs to a group of medicines called steroids, also known as

corticosteroids. These corticosteroids occur naturally in the body and help to maintain health and well-being.

BETANOID SYRUP is used for the treatment of inflammatory conditions where a steroid is indicated.

2. What you need to know before you take BETANOID SYRUP

You should not take BETANOID SYRUP:

- if you are hypersensitive (allergic) to betamethasone or any of the other ingredients of BETANOID SYRUP (listed in section 6).
- if you are hypersensitive (allergic) to other corticosteroids.
- if you have been told by your doctor that you have a serious fungal infection (systemic fungal infection).
- if you have or have had sores in your stomach with symptoms such as indigestion, nausea or vomiting (peptic ulcer).
- if you have thinning of the bones (osteoporosis).
- if you have mental disorders (psychosis, severe psychoneuroses).
- if you have an active or inactive bacterial infection typically affecting the lungs (tuberculosis).
- if you have any acute viral infections including herpes zoster(shingles) or herpes simplex ulceration of the eye.
- if you need to go for a vaccination or have just been vaccinated.
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with BETANOID SYRUP:

- If you have recently had a heart attack.
- if you have an underactive thyroid gland (hypothyroidism).

- if you have myasthenia gravis (a disease which causes muscle weakness).
- If you have, or suspect that you may have, an infection or any infective diseases.
- If you have recently been in contact with someone who has chickenpox, shingles, or measles, or recently had, or have chickenpox, shingles, or measles, yourself. You should consult your doctor if you suspect any of these.
- If you have been taking this medicine or any other corticosteroids repeatedly for a long period of time.
- If you have been receiving high doses of this medicine or other corticosteroids, or repeatedly taking this medicine in the evenings.
- If you experience any trauma or will be going for a surgical procedure while taking this medicine.
- If you are post-menopausal.
- If you have high blood pressure or other heart problems.
- If you have diabetes mellitus or someone in your family has diabetes.
- If you have suffered from tuberculosis (TB).
- If you have an eye infection or suffer from increased pressure in your eye (glaucoma) (or a family history of glaucoma), blurred vision or other visual disturbances.
- If you have ever experienced muscle weakness after taking/receiving a corticosteroid, such BETANOID SYRUP.
- If you have liver failure.
- If you have kidney problems.
- If you suffer from seizures (fits).
- If you are elderly.
- If you suffer from inflammatory illnesses, sores, infections, or blockage of the digestive tract (diverticulitis).

- If you have suffered from clotting disorders.
- If you (or someone taking this medicine) show any signs of mental health changes problems, talk to your doctor. This is particularly important if you are depressed or might be thinking about suicide. Mental health problems, which can be serious, can occur while taking this medicine and they might need treatment.
- If you have a tumour of the adrenal gland (pheochromocytoma).
- If you are taking potassium containing supplements.
- If your diet consists of a high salt intake.

Children and adolescents

Caution is advised when giving this medicine to a child as they may experience more severe side effects.

BETANOID SYRUP may cause growth retardation in infancy, childhood and adolescence, which may be irreversible.

Other medicines and BETANOID SYRUP

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

Tell your doctor if you are taking any of the following:

- Anticholinesterase medicines, (used in the treatment of myasthenia gravis), as the effect of these medicines may be reduced.
- Phenobarbitone, phenytoin, carbamazepine, primidone, medicines used to treat epilepsy may result in BETANOID SYRUP being less effective.
- Aminoglutethimide used to treat certain patients with Cushing's syndrome and some types of cancer.
- Rifampicin and rifabutin, medicines used to treat tuberculosis (TB) may result in BETANOID SYRUP being less effective.

- Ephedrine, a medicine in cold and flu medicine may result in BETANOID SYRUP being less effective.
- The effects of medicines used to treat hypertension including water tablets (diuretics), may be reduced.
- Antidiabetic medicines including insulin may not be as effective.
- Warfarin and aspirin, used to prevent clotting of your blood.
- Theophylline, used to treat lung conditions.
- Carbenoxolone, a medicine used to treat ulcers in your digestive tract.
- Amphotericin B, a medicine used to treat fungal infections.
- Cardiac glycosides e.g., digoxin, medicine used to treat heart conditions.
- Oral contraceptives, used to prevent pregnancy.
- Cobicistat and ritonavir, medicines used to treat HIV.
- Mifepristone, a medicine used to protect the digestive tract, will result in a reduced effect of BETANOID SYRUP for 3 to 4 days after taking mifepristone.
- Somatropin, a medicine used to treat growth failure in children, may not be effective.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs) used to treat inflammatory conditions should be used very cautiously when taken with BETANOID SYRUP as the risk of stomach bleeding increases.
- Vecuronium, a medicine used as a muscle relaxant, may not be as effective.
- Fluoroquinolones, medicines used to treat bacterial infections, as your risk of tendon ruptures increases.
- Quetiapine, a medicine used to treat mental conditions, may not be as effective.
- Tretinoin, used to treat skin conditions, may not be as effective.

Tell your doctor if you need to go for a cholecystography (a radiological procedure used to visualise the gallbladder and biliary tract), as the effect of BETANOID SYRUP may

reduce cholecystographic X-ray media.

Pregnancy, breastfeeding, and fertility

You should not take BETANOID SYRUP if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking BETANOID SYRUP.

Driving and using machines

BETANOID SYRUP can cause blurred vision and is expected to influence your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent BETANOID SYRUP may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BETANOID SYRUP affects you (see section 4).

BETANOID SYRUP contains sucrose and glucose

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

3. How to take BETANOID SYRUP

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

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

Your doctor will prescribe a dose specific to your condition and response to treatment.

Your doctor will tell you how long your treatment with BETANOID SYRUP will last. If you have the impression that the effect of BETANOID SYRUP is too strong or too weak, tell

your doctor or pharmacist.

If you take more BETANOID SYRUP than you should

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

If you forget to take BETANOID SYRUP

Do not take a double dose to make up for forgotten individual doses.

If you have missed a dose of BETANOID SYRUP, take the dose that you have missed as soon as you remember.

If you stop taking BETANOID SYRUP

Do not stop taking BETANOID SYRUP without first consulting your doctor, as you may experience symptoms such as fever, muscle pain, joint pain, flu-like symptoms, swelling/redness of the eyes, and loss of weight.

4. Possible side effects

BETANOID SYRUP can have side effects.

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

If any of the following happens, stop taking/giving BETANOID SYRUP 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,
- blistering of the skin, mouth, eyes, and genitals as these may be due to a serious

allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious reaction to BETANOID SYRUP. 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:

- swelling that makes the face round (moon face), a hump behind the shoulder (buffalo hump), unwanted male-pattern hair growth on a woman's face, chest and back (hirsutism), weight gain, flushing, and acne, as these are all symptoms of Cushing's syndrome,
- fatigue, trouble sleeping, allergies, weakened immune function, and food cravings, as these are symptoms of hypothalamic-pituitary- adrenal (HPA) axis suppression,
- growth suppression in, babies, children and adolescents,
- increased pressure in your eye (glaucoma),
- swelling and fluid build-up near the eyes and brain called papilloedema (this may result in a throbbing headache which may be worse upon waking up, coughing or sudden movement and patchy vision with blind spots and possible lack of colour vision) (increased intracranial pressure),
- disorders that affect the brain as well as the nerves found throughout the human body and the spinal cord (neurological disturbances),
- cataracts (cloudy window over your eye),
- redness and swelling of the white part of the eye, blurred vision, and tearing as this could be signs of corneal or scleral thinning,
- chest pain that may feel like pressure, difficulty breathing, cold hands and feet after recently having a heart attack as these are signs of myocardial rupture,
- burning pain in the chest, nausea (feeling sick), indigestion, bloating, as these

may be signs of oesophageal ulceration,

- pain or discomfort in the abdomen, feeling uncomfortably full too soon while eating a meal with black stools (peptic ulcer),
- severe upper stomach pain with nausea or vomiting, as this may be a sign of a swollen pancreas (pancreatitis),

- low blood levels of potassium which can cause muscle weakness, twitching, confusion, light-headedness, or abnormal heart rhythm (hypokalaemia, hypokalaemic alkalosis),
- death of bone tissue due to lack of blood supply (avascular osteonecrosis), bone and back fractures, death of the tips of the long bones (femur and humerus);
- blocking of a blood vessel by a blood clot dislodged from its site of origin with symptoms such as shortness of breath, chest pain, cough, or fainting (thromboembolism/ thromboembolic complications),
- suicidal thoughts, feeling, seeing, or hearing things which do not exist (hallucinations), and worsening of a psychiatric condition called schizophrenia (psychotic reactions).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- feel depressed, feeling irritable, feeling anxious, having trouble sleeping or staying asleep,
- having strange and frightening thoughts, changing how you act or having feelings of being alone.

Side effects with an unknown frequency:

- Increased susceptibility and severity of infections, masking of infections, worsening of viral and fungal eye infections,
- repeat of infections such as TB,
- an increase in the number of white cells in the blood, especially during an infection with symptoms such as fever, bleeding, or bruising (leucocytosis),
- menstrual irregularities/ disturbances such as the absence of a menstrual period (amenorrhoea),
- salt and fluid retention with symptoms such as swelling, or inability of the small intestine to completely process the nutrient carbohydrate (a classification that includes sugars and starches) (decreased carbohydrate tolerance), high blood sugar levels (hyperglycaemia),
- high blood pressure with symptoms such as flushed face, headache, blurred vision, tiredness, confusion, and difficulty breathing (hypertension),
- swelling of the stomach (abdominal distention), hiccups, discomfort in the stomach, fungal infection (candidiasis),
- impaired wound healing, thinning of skin, increased bruising, spider veins (telangiectasia) stretch marks, acne,
- muscle weakness (myopathy), thinning of bones (osteoporosis) bone fractures, tendon rupture,
- excessive sweating (hyperhidrosis), a general sense of being unwell (malaise),
- nitrogen depletion with symptoms such muscle weakness and wasting, brittle hair and hair loss.

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, pharmacist, or nurse. You can also report side effects 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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of BETANOID SYRUP.

5. How to store BETANOID SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use

Do not store in a bathroom.

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 BETANOID SYRUP contains

The active substance per 5 ml of BETANOID SYRUP is 0,60 mg of betamethasone.

The other ingredients are citric acid monohydrate (for pH adjustment), colour spectoral sunset yellow (C.I. 15985), flavour passion fruit, flavour raspberry superb, glucose, propylene glycol, purified water, sodium benzoate, sodium chloride, sucrose.

Preservative: Sodium benzoate 0,15 % *m/v*

Contains sugar: Glucose 1,5 g and sucrose 0,625 g

What BETANOID SYRUP looks like and contents of the pack

BETANOID SYRUP is a clear orange syrup with a fruity flavour.

100 ml are packed into an amber polyvinyl chloride or glass bottle and sealed with a white screw-on polypropylene cap with or without an expanded polyethylene liner. The bottle is placed in an outer cardboard together with a leaflet.

500 ml are packed into an amber polyvinyl chloride bottle and sealed with a white screw-on cap with a polypropylene liner. The bottle is placed in an outer cardboard together with a leaflet.

Not all packs or pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

4 April 2024

Registration number

27/21.5.1/0491

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and

Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

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Namibia: NS2 04/21.5.1/0089

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