1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

BETADEXAMINE TABLETS 0,25 mg/2 mg

Betamethasone, dexchlorpheniramine maleate

Contains sugar: Anhydrous lactose 174,75 mg

Read all of this leaflet carefully before you start taking BETADEXAMINE TABLETS

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

1. What BETADEXAMINE TABLETS is and what it is used for

BETADEXAMINE TABLETS belongs to a group of medicines known as corticosteroids in combination with anti-histamines. BETADEXAMINE TABLETS is used for the treatment of allergic rhinitis (hay fever) and certain allergic skin conditions.

2. What you need to know before you take BETADEXAMINE TABLETS

Do not take BETADEXAMINE TABLETS

- if you are hypersensitive (allergic) to betamethasone, dexchlorpheniramine or any of the other ingredients of BETADEXAMINE TABLETS (listed in section 6).
- if you have an infection.
- if you take medicines referred to as Monoamine Oxidase Inhibitors (MAOIs), used to treat depression.

BETADEXAMINE TABLETS should not be administered to new-borns, premature infants or children (see section titled Children below).

Warnings and precautions

Take special care with BETADEXAMINE TABLETS

- BETADEXAMINE TABLETS may lead to disturbed concentration and excessive sleepiness (drowsiness).
- If you recently had a heart attack.
- If you need to go for a vaccination or have been exposed to measles.
- If you suffer from inflammatory illnesses, sores, infections or blockage of the digestive tract (ulcerative colitis, peptic ulcer, abscess, diverticulitis, pyloroduodenal obstruction).
- If you suffer from tuberculosis (TB).
- If you have kidney problems.
- If you suffer from a tumour of the adrenal gland (Pheochromocytoma).

- If you have high blood pressure.
- If you suffer from osteoporosis (thinning of the bones).
- If you suffer from an overactive or underactive thyroid gland (hyperthyroidism, hypothyroidism).
- If you have scarring on your liver (cirrhosis).
- If you have an eye infection or suffer from increased pressure in your eye (glaucoma).
- If you suffer from myasthenia gravis (weakness of the muscles).
- If you suffer from a heart disease.
- If you have diabetes mellitus or someone in your family has diabetes.
- If you are an elderly patient.
- If you suffer from mental disorders.
- If you suffer from muscle weakness (muscle disease).
- If you have liver failure.
- If you suffer from seizures.
- If you have an enlarged prostate gland which can cause difficulty in urinating (prostatic hypertrophy).

Children

There is no experience with BETADEXAMINE TABLETS in children younger than 12 years. BETADEXAMINE TABLETS should not be administered to new-borns, premature infants or children as it may affect their growth permanently (see section titled Do not take BETADEXAMINE TABLETS).

Other medicines and BETADEXAMINE TABLETS

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:

- Phenobarbitone, phenytoin, carbamazepine, primidone, aminoglutethimide, medicines used to treat epilepsy.
- Rifampicin and rifabutin, medicines used to treat tuberculosis (TB).
- Ephedrine, a medicine in cold and flu medicine.
- Medicines used to treat hypertension including water tablets.
- Oral contraceptives, used to prevent pregnancy.
- Digoxin, a medicine used to treat heart conditions.
- Medicines used to treat ulcers in your digestive tract.
- Theophylline, used to treat lung conditions.
- Amphotericin B, a medicine used to treat fungal infections.
- Warfarin and aspirin, used to prevent clotting of your blood.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs) used to treat inflammatory conditions.
- Antidiabetic medicines including insulin.
- Mifepristone, a medicine used to protect the digestive tract or for abortion.
- Vecuronium, a medicine used as a muscle relaxant.
- Fluoroquinolones, medicines used to treat bacterial infections.
- Quetiapine, a medicine used to treat mental conditions.
- Cobistat and ritonavir, medicines used to treat HIV.
- Tretinoin, used to treat skin conditions.
- Anticholinesterase medicines, used in the treatment of myasthenia gravis.
- If you need to go for a cholecystography (a radiological procedure used to visualise the gallbladder and biliary tract).
- Alcohol, tricyclic antidepressants and other medicines that suppresses your central nervous system.

BETADEXAMINE TABLETS should be discontinued approximately 48 hours prior to skin testing procedures since these medicines may prevent or diminish otherwise positive reactions to skin tests.

BETADEXAMINE TABLETS with food, drink and alcohol

BETADEXAMINE TABLETS should be taken after meals.

BETADEXAMINE TABLETS should not be taken with alcohol. Taking BETADEXAMINE TABLETS with alcohol will lead to aggravation of drowsiness and impaired concentration.

Pregnancy, breastfeeding and fertility

You should not take BETADEXAMINE TABLETS 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 BETADEXAMINE TABLETS.

Driving and using machines

BETADEXAMINE TABLETS may cause drowsiness 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 BETADEXAMINE TABLETS 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 BETADEXAMINE TABLETS affects you (see section 4).

BETADEXAMINE TABLETS contains lactose anhydrous

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

3. How to take BETADEXAMINE TABLETS

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

Always take BETADEXAMINE TABLETS 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.

BETADEXAMINE TABLETS are only to be used for short-term treatment (less than 5 days).

BETADEXAMINE TABLETS should not be mixed with other mixtures.

BETADEXAMINE TABLETS should be taken after meals.

The usual dose of BETADEXAMINE TABLETS in adults and children over 12 years of age is 1 (one) to 2 (two) tablets four times daily after meals and at bedtime. The dose should not exceed 8 (eight) tablets per day. Treatment should not exceed 5 days.

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

If you take more BETADEXAMINE TABLETS 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 BETADEXAMINE TABLETS

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

If you have missed a dose of BETADEXAMINE TABLETS, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

BETADEXAMINE TABLETS can have side effects.

Not all side effects reported for BETADEXAMINE TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking BETADEXAMINE TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking/using BETADEXAMINE TABLETS 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 BETADEXAMINE TABLETS. 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:

- Severe pain, rapid or immediate bruising, marked weakness and deformity of the area as these may be symptoms of a tendon rupture.
- Excessive bruising, prolonged bleeding from cuts, bleeding from your gums or nose as these may be symptoms associated with low platelet levels.
- Repeated fever and infections as these may be symptoms associated with a low white blood cells levels.
- Fever as this may be a sign of an underlying infection.

- Seizures (fits).
- Pain or infection in the eye/s.
- Cataracts (cloudy window over your eye).
- Hearing loss (acute labyrinthitis).
- Involuntary repetitive movements of the mouth and face (facial dyskinesias).
- Growth retardation, when a baby or child stops growing.
- Thinning of the bones (osteoporosis) or breaking of the bones (fractures).
- Chest pain and/or changes in the way your heart beats, for example, if you notice it beating faster.
- Increased, difficulty or hesitation to urinate.

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:

- Drowsiness.

Side effects with an unknown frequency:

- Confusion, restlessness, excitation, nervousness, irritability, inability to sleep (insomnia), intense excitement (euphoria);
- dizziness, sleepiness, disturbed coordination;
- hysteria, depression, seeing and hearing things that are not real (hallucinations), inability to concentrate, anxiety;
- shaking movements (tremors), pins and needles in the fingers and toes (paraesthesia), inflammation of the nervous system (neuritis);
- increased or lowered response of the muscles to stimuli (hyperreflexia/hyporeflexia);
- headache, blurred vision, ringing in the ear/s, double vision, dilated pupils;
- low blood pressure;

- dryness of the nose, mouth and throat;
- thickening of bronchial secretions, tightness of the chest, wheezing, nasal stuffiness;
- fungal infection of the skin, mouth, throat, gut or vagina (candidiasis);
- loss of appetite, nausea, vomiting, diarrhoea, constipation, absence of saliva (xerostomia), appetite stimulation;
- impaired healing of wounds, thinning of the skin, acne, red lines on the skin (telangiectasia), lines on the skin (stria), photosensitivity;
- muscle weakness, general feeling of unwellness (malaise), hiccups, excessive perspiration, chills, physical or mental weariness (lassitude);
- early menstruation, menstrual irregularity;
- excessive growth of dark or coarse hair in a male like pattern in women e.g. on the face, chest and back (hirsutism).

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: 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 BETADEXAMINE TABLETS.

5. How to store BETADEXAMINE TABLETS

Store all medicines out of reach of children.

Store at or below 30 °C.

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 BETADEXAMINE TABLETS contains

The active substances are 0,25 mg betamethasone and 2 mg dexchlorpheniramine maleate.

The other ingredients are anhydrous lactose, corn starch, gelatin, magnesium stearate.

Contains sugar: Anhydrous lactose 174,75 mg

What BETADEXAMINE TABLETS looks like and contents of the pack

BETADEXAMINE TABLETS are white to off-white round tablets debossed with A24 on one side and a score line on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Round polypropylene tube with a polyethylene cap and desiccant stopper, in a carton. Pack size of 30 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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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

Tel: 0800 118 088

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