1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

BETADEXAMINE

Liquid

Read all of this leaflet carefully before you start taking BETADEXAMINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- BETADEXAMINE 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 BETADEXAMINE CONTAINS

The active substances are betamethasone 0,25 mg and dexchlorpheniramine maleate 2,0 mg per 5 ml of BETADEXAMINE liquid.

The other ingredients are Colour sunset yellow (C.I. 15985), citric acid monohydrate, disodium edetate, flavour peach, glycerol, polysorbate 80, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sorbitol solution (70 %).

BETADEXAMINE is preserved with sodium benzoate 0,1 % *m/v*.

Contains sugar: Sorbitol solution (70 %) 2 g/5 ml

Contains sweetener: Saccharin sodium 3,5 mg/5 ml

WHAT BETADEXAMINE IS USED FOR

BETADEXAMINE is used as a second-line therapy when antihistamines only are not effective for the treatment of:

- Short-term treatment of allergic rhinitis (hay fever).
- Allergic skin disorders that respond to cortisone-like medicines, as contained in BETADEXAMINE.

BEFORE YOU TAKE BETADEXAMINE

Do not take BETADEXAMINE:

- If you are hypersensitive (allergic) to cortisone medicines including betamethasone or to antihistamines, including dexchlorpheniramine or any of the other ingredients of BETADEXAMINE (see WHAT BETADEXAMINE CONTAINS).
- If you have a fungal infection, BETADEXAMINE can cause slower healing or worsen existing infections.
- If you are taking monoamine oxidase inhibitor (MAOI) type antidepressant medicines or within 2 weeks after use of a MAOI, as the combined use of these two medicines may prolong and intensify side effects.
- In newborn or premature babies, as young infants are more prone to serious side effects such as excitation or seizures.
- Safety in children below the age of 12 years has not been established.
- If you suffer from glaucoma (increased pressure in the eye).

Take special care with BETADEXAMINE:

- BETADEXAMINE is not indicated for treatment of longer than five days.
- BETADEXAMINE must be used only for the period that your doctor has specified.
- BETADEXAMINE can cause drowsiness. This may be worsened by the simultaneous intake of alcohol or other medicine that act on the central nervous system.

- Long term use of BETADEXAMINE and particularly in high doses can lead to an increase of cortisol in the blood with signs like ‘buffalo hump’, puffy/rounded face and relatively slender arms and legs, growth and development retardation in young children. Adrenal crisis (a life-threatening condition) has been reported in patients of all ages. Symptoms include, but are not limited to, confusion, coma, darkening of the skin, abdominal pain, fatigue, high fever, joint pain, low blood pressure, vomiting.
- If you have a stomach ulcer or other stomach or intestinal problems or ulcerative colitis, as BETADEXAMINE may cover up symptoms if these conditions get worse.
- If you have tuberculosis, systemic fungal infections, bacterial infections or viral infections of the eye as BETADEXAMINE can slow healing or worsen existing infections.
- If you have heart disease, high blood pressure or kidney disease as BETADEXAMINE may cause the body to retain more water, worsening these conditions.
- If you have osteoporosis (a condition of fragile bone with an increased susceptibility to fracture), BETADEXAMINE may cause the body to lose more calcium.
- If you have thyroid problems or myasthenia gravis (a condition that interferes with the messages the nerves send).
- If you have prostate problems, urination problems or glaucoma/cataracts antihistamines as contained in BETADEXAMINE can worsen these conditions.
- If you have diabetes mellitus, as BETADEXAMINE may interfere with blood sugar control and your doctor may have to adjust the dosage for your anti-diabetic medication.
- If you have any mood or mental problems, BETADEXAMINE may worsen these disorders.
- Elderly patients are more prone to side effects from BETADEXAMINE.
- Your doctor may advise on dietary salt restrictions, and potassium supplementation may be considered.
- You should not receive any vaccination procedures whilst on BETADEXAMINE, especially if you are on higher doses.
- If you suffer from epilepsy, as occasional convulsions have been reported.

Taking BETADEXAMINE with food and drink:

Take BETADEXAMINE with food to lessen stomach upset. Stomach problems may be more likely to occur if you drink alcohol while you take BETADEXAMINE. Antihistamines will also add to the effects of alcohol, possibly increasing drowsiness. It is best to avoid drinking alcohol while taking BETADEXAMINE.

Pregnancy and breastfeeding

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

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking BETADEXAMINE.

Fertility

BETADEXAMINE therapy may alter the motility and number of spermatozoa which may reduce your fertility.

Driving and using machinery

The antihistamine in BETADEXAMINE may cause drowsiness, dizziness, loss of concentration or blurred vision. Make sure you know how you react to BETADEXAMINE before you drive, use machines or do anything that could be dangerous if you are not alert or able to see properly.

Important information about some of the ingredients in BETADEXAMINE

BETADEXAMINE contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take BETADEXAMINE.

Taking other medicines with BETADEXAMINE

Always tell your healthcare provider if you are taking any other medicines (this includes

complementary or traditional medicines).

BETADEXAMINE should not be taken together with:

- Monoamine oxidase inhibitor (MAOI)-type antidepressant medicines or within two weeks of taking MAOI (see Do not take BETADEXAMINE). The combined use of these two medicines may prolong and intensify side effects.
- Alcohol and other medicines that cause sedative effects or drowsiness, as combined use of these medicines can worsen drowsiness.
- Anticholinergics (medicines for abdominal or stomach cramps, some antihistamines), as combined use of these medicines can worsen side effects such as dry mouth.
- Non-steroidal anti-inflammatory medicines as combined use may increase the risk of stomach problems.
- Vaccines, especially live viral vaccines. You should not have any vaccines without speaking to your doctor first.
- Blood thinners (e.g. warfarin), diuretics (water tablets), some heart medicines, amphotericin B, some medicines for epilepsy, rifampicin, medicines for diabetes mellitus or oestrogens.
- BETADEXAMINE can decrease the blood levels of aspirin. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinaemia (a blood-clotting disorder).
- Concomitant glucocorticoid therapy may inhibit the response to somatotropin (growth hormone).

HOW TO TAKE BETADEXAMINE

Always take BETADEXAMINE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and children over 12 years

The dosage of BETADEXAMINE depends on the condition being treated and your response to

therapy.

BETADEXAMINE is for short-term use only (not more than 5 days).

BETADEXAMINE should not be mixed with other mixtures.

The usual dose for adults and children over 12 years of age is:

Take 5 ml to 10 ml four times daily after meals and at bedtime. The dose should not exceed 40 ml daily.

Shake bottle well before use.

Treatment should not exceed 5 days.

Do not take another course of treatment with BETADEXAMINE within 28 days unless your doctor specifically tells you to do so.

If you have the impression that the effect of BETADEXAMINE is too strong or too weak, speak to your doctor or pharmacist.

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

Not for use in children under 12 years of age.

If you take more of BETADEXAMINE 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

If you miss a dose of BETADEXAMINE, take it as soon as you remember that day. If you only remember the next day, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with BETADEXAMINE is stopped

If BETADEXAMINE has been taken for a long time (contrary to the recommended dosing schedule), a withdrawal syndrome can occur if you suddenly stop taking the medicine. In this case, your doctor will advise you to reduce the dose slowly before stopping the medicine completely.

POSSIBLE SIDE EFFECTS

BETADEXAMINE can have side effects.

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

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

- Cough, difficulty swallowing, dizziness, fast heartbeat, hives, itching, puffiness or swelling of the eyelids or around the eyes, face, lips or tongue, shortness of breath, skin rash, tightness in the chest, unusual tiredness or weakness and wheezing;
- hypersensitivity reactions.

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

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

- Cushing's Syndrome (e.g. 'buffalo hump', round/puffy face);
- liver problems; symptoms include, but are not limited to, abdominal or stomach pain, chills, clay-coloured stools or dark urine, diarrhoea, dizziness, fever, headache, itching;
- convulsions (seizures/fits);
- burning, prickly sensation, or tingling feeling on the body;
- sore throat, fever, unusual bleeding or bruising, as this can be indicative of blood problems;
- adrenal crisis (a life-threatening condition) has also been reported in patients of all ages. Symptoms include, but are not limited to, confusion, coma, darkening of the skin, abdominal pain, fatigue, high fever, joint pain, low blood pressure, vomiting;
- blood disorders, for example an abnormal breakdown in red blood cells, a decrease in the number of white blood cells, a decrease in the number of platelets;
- abnormal heart rhythm, palpitations;
- constant pain in the upper abdomen that radiates to the back as these may be symptoms of pancreatitis;
- increased pressure in the eye with symptoms like blurry vision or severe eye pain;
- breathing difficulty, chest pain, cough with mucous, coughing up blood, excessive sweating, weight loss as these may be symptoms of pulmonary tuberculosis;
- decrease in bone strength resulting in bone fractures.

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects have been reported frequently:

- Increased occurrence of infection;
- decreased body growth;

- depression;
- profound sense of wellbeing;
- increase in blood pressure;
- gastric irritation (a symptom of stomach disorders with symptoms like abdominal pain and gas), nausea, vomiting, indigestion, increased appetite;
- impaired skin healing, decrease in skin thickness;
- state or feeling of weariness, diminished energy, or listlessness, incoordination, dizziness, headache, slowdown in thoughts;
- blurred vision;
- thickening of the mucus, dryness of nasal mucosa, dry mouth, constipation, increased gastric reflux;
- urinary difficulty or retention.

The following side effects have been reported less frequently:

- Low or high blood sugar;
- low potassium blood levels;
- salt and fluid retention resulting in swelling of the feet, hands, tummy (abdomen), breasts and face;
- nervousness, restlessness;
- cataract (a clouding of the lens in the eye leading to a decrease in vision. Symptoms may include faded colors, blurry vision, halos around light, trouble with bright lights, and trouble seeing at night);
- stomach ulcers, the major symptom of an ulcer is a burning or gnawing feeling in the stomach area that lasts between 30 minutes and 3 hours;
- sleep disturbances, confusion;
- ringing in the ears;
- low blood pressure;

- hair loss;
- muscle weakness;
- rhythmic muscle contraction/s or involuntary muscle contraction/s;
- fluid and electrolyte disturbances;
- sweating.

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

STORING AND DISPOSING OF BETADEXAMINE

Store at or below 25 °C, in a well-closed container

Protect from light

Do not store in bathroom

Do not use after the expiry date stated in label

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Keep in original packaging until required for use

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF BETADEXAMINE

100 ml round, amber, glass bottle with white, tamper-evident, polypropylene screw cap. The bottle is placed in an outer cardboard carton together with a leaflet

Betadexamine: 100 ml, high density polyethylene, brown bottle with a white, low density polyethylene, snap-cap closure. The bottle is placed in an outer cardboard carton together with a leaflet.

Not all packs are necessarily marketed.

IDENTIFICATION OF BETADEXAMINE

A bright, clear orange solution with a fruity peach odour

REGISTRATION NUMBER

A40/21.5.4/0623

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

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Woodmead 2191

Hotline: 0800 122 912

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