1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ADCO LABETALOL 5 mg/ml solution for injection

Each ml contains 5 mg labetalol hydrochloride

Contains sugar: Glucose anhydrous 45 mg/ml

Read all of this leaflet carefully before you are given ADCO LABETALOL 5 mg/ml

- 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.

What is in this leaflet

1. What ADCO LABETALOL is and what it is used for

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ADCO LABETALOL solution for injection belongs to a group of medicines called beta-blockers.

ADCO LABETALOL solution for injection works by causing the heart to beat more slowly and with less force. It also widens the arteries in the body. This helps lower the pressure of the blood as it travels around the body. The result is a rapid lowering of a person's blood pressure.

ADCO LABETALOL 5 mg/ml solution for injection is given in hospital and can be used to:

- Lower very high blood pressure quickly, including lowering very high blood pressure in pregnant women
- Keep your blood pressure down during an operation.

2. What you need to know before you use ADCO LABETALOL

ADCO LABETALOL should not be administered to you if:

- You are hypersensitive (allergic) to labetalol or to any of the other ingredients of ADCO LABETALOL (listed in section 6)
- Your heart cannot maintain adequate circulation of blood (cardiogenic shock)
- You have heart failure that is out of control or not responding to treatment with digitalis (digoxin)
- You have a problem that is common in the elderly, related to poor control of the working of your heart (sick sinus syndrome)
- You have a heart defect that leads to a decreased function of the heart (heart block)
- You suffer from angina (chest pains) when at rest
- You suffer from wheezing, obstructive airways disease or asthma – administration of ADCO LABETALOL to you can make your breathing worse

- You have a tumour near your kidneys (phaeochromocytoma)
- You have increased acid levels in the blood (metabolic acidosis)
- You have a weak heart or a very slow heartbeat (less than 45 or 50 beats per minute)
- You have low blood pressure (hypotension)
- You have very bad circulation, especially in your hands and feet and if you have a condition called Raynaud's phenomenon (decreased blood flow to certain areas causing it to become numb and cold)
- Your heart has difficulty pumping the proper amount of blood to the body's tissues
- ADCO LABETALOL should not be used by women who are breastfeeding their infants.

Warnings and precautions

Special care should be taken with ADCO LABETALOL if:

- You are allergic to any other medicines, insect stings, foods, dyes or preservatives. This is particularly important if you have had a sudden severe (anaphylactic) reaction to anything in the past
- You are pregnant or plan to become pregnant. If you are trying to get pregnant and need ADCO LABETALOL for another condition, please tell your doctor
- You have kidney or liver problems
- You are about to receive an anaesthetic: as labetalol may mask the effects of a sudden loss of blood
- You are scheduled for cataract surgery as ADCO LABETALOL may affect your pupils during this procedure. Please tell your eye surgeon before your surgery about your treatment with labetalol. You do not need to stop treatment with this medicine unless your surgeon advises otherwise

- You have bad circulation in your hands or feet
- You are having a medical procedure called MIBG scintigraphy
- You have hypovolaemia (a state of decreased blood volume)
- You have thyrotoxicosis (excess of thyroid hormone in the body)
- You have ever suffered from a skin condition and or dry eyes
- You are elderly (65 years and over)
- You suffer or have suffered from any serious allergic reactions in the past
- You have any heart conditions or are taking medicines for stimulating the heart e.g. adrenaline
- You are taking other beta-blockers.

ADCO LABETALOL should be used with caution in patients suffering from diabetes mellitus. A slight increase in blood sugar levels occurs following the administration of ADCO LABETALOL and the possibility of interactions of ADCO LABETALOL with insulin and/or anti-diabetic medicines.

ADCO LABETALOL contains glucose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Children and adolescents

Safety and efficacy in children have not been established.

Other medicines and ADCO LABETALOL

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

Tell your healthcare provider if you are taking any of the following medicines:

- Medicines used to treat your heart or blood pressure (such as digitalis e.g. digoxin, clonidine, hydralazine, disopyramide, quinidine, amiodarone, calcium antagonists such as verapamil, alpha blockers such as doxazosin, diltiazem, nifedipine, ACE inhibitors, angiotensin-II antagonists, xamoterol and diuretics (water tablets))

- Medicines to treat depression (such as monoamine oxidase inhibitors or tricyclic antidepressants)
- Anxiolytic and hypnotic medicines for anxiety and sedation
- NSAIDs, corticosteroids or other medicines to treat pain or inflammatory conditions
- Cimetidine used to treat stomach ulcers
- Insulin or oral anti-diabetic medicines
- Anaesthetic medicines (such as cyclopropane, trichloroethylene, alcohol, barbiturates)
- Phenothiazines such as chlorpromazine
- Antimalarial medicines such as halofantrine, mefloquine or quinine
- Medicines for stimulating the heart e.g. adrenaline
- Ergot derivatives and cholinesterase inhibitors used to treat Parkinson’s disease
- Tropisetron used to treat nausea
- Alprostadil and moxisylyte to treat impotence
- Aldesleukin for the treatment of secondary cancer of the kidney

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- Hormones such as oestrogen and progesterone used as contraceptives or for hormone replacement therapy.

Taking ADCO LABETALOL at the same time as the medicines mentioned for treating your heart or blood pressure, can lead to a severe drop in blood pressure, reduced heart rate, heart failure or heart block. It is important to tell your doctor if you are taking these or any of the other medicines listed above.

The results of blood or urine tests may be affected by taking ADCO LABETALOL. If you need to have a blood or urine test, tell your doctor that you have been given ADCO LABETALOL.

Pregnancy, breastfeeding and fertility

Pregnancy and breastfeeding

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 this medicine.

Safety in pregnancy and breastfeeding has not been established.

ADCO LABETALOL is sometimes used to control pre-eclampsia (high blood pressure brought on by pregnancy). ADCO LABETALOL may have unwanted effects in an unborn or new-born baby. If you are trying to get pregnant and need ADCO LABETALOL for another condition, please tell your doctor.

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ADCO LABETALOL is excreted in breast milk. Adverse events such as sudden death syndrome, diarrhoea and low blood sugar may occur in breast-fed new-borns. Women should not breastfeed their infants while receiving ADCO LABETALOL injection.

Fertility

No data on male and female fertility is available.

Driving and using machines

It is not always possible to predict to what extent ADCO LABETALOL may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which ADCO LABETALOL affects you.

3. How to use ADCO LABETALOL

ADCO LABETALOL is usually only given to patients in hospital by a doctor or anaesthetist. It may be given as an injection into a vein.

Your doctor will decide how the ADCO LABETALOL will be given to you and the correct dose for you.

You should only be given this medicine if you are lying down.

You should avoid sitting upright for three hours after being given ADCO LABETALOL as you may feel very dizzy and lightheaded.

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While you are having ADCO LABETALOL your doctor may check your heart rate, blood pressure and breathing, to check your medicine is working properly.

You will not be expected to give yourself ADCO LABETALOL. It will be given to you by a person who is qualified to do so.

If you have the impression that the effect of ADCO LABETALOL is too strong or too weak, tell your doctor or healthcare worker or pharmacist.

If you are given more ADCO LABETALOL than you should

Since a healthcare provider will administer ADCO LABETALOL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take ADCO LABETALOL

Since a healthcare provider will administer ADCO LABETALOL, it is unlikely that the dose will be missed.

4. Possible side effects

ADCO LABETALOL can have side effects.

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

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If any of the following happens, administration of ADCO LABETALOL should be stopped. Therefore, you should tell your doctor or healthcare worker immediately.

- Hypersensitivity (rash, pruritus (itching), angioedema (swelling of your eyelids, face or lips))
- Heart failure, abnormal heart rhythm, hypotension (low blood pressure)
- Dyspnoea (difficulty in breathing), asthma
- Poor circulation in the hands, cold or blue extremities, numbness or tingling of the extremities
- Jaundice causing discomfort and tenderness in the upper abdomen, yellowing of the skin and whites of the eyes
- Thrombocytopenia causing nosebleeds or bleeding in the mouth or bruising because your blood does not clot as it should
- Mental disturbances such as delusions and altered thought patterns, hallucinations or confusion.

These are all very serious side effects. If you have them, you may have had a serious reaction to LABETALOL ADCO ADCO LABETALOL 5 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Depression or exhaustion (lethargy)
- Problems with the immune system (e.g. systemic lupus erythematosus) causing shortness of breath, joint pain, or a rash on the cheeks and arms that worsens with sun exposure
- Flat topped bumps on your skin that join up into scaly patches (lichenoid rash)

- High blood potassium levels (hyperkalaemia) especially if you have reduced kidney function
- Sleep disturbances including nightmares
- Blurred vision or dry eyes
- Cramps, muscle disease (toxic myopathy) causing weakness and wasting of the muscles in the arms and legs
- Difficulty passing urine or not being able to pass urine
- Not being able to ejaculate
- Drug fever making you feel hot and flu-like, thyrotoxicosis (excessive production of thyroid hormones by the thyroid gland); low blood sugar; hair loss; this may grow back after stopping treatment.

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:

- Tiredness, dizziness
- Tingling of the scalp, or a blocked nose
- Swollen ankles or sweating
- Worsening of psoriasis (skin disease marked by red, itchy, scaly patches)
- Stomach pain, feeling sick or being sick and diarrhoea
- Heart failure
- Low blood pressure may occur with confusion and disorientation if you are allowed to assume the upright position within three hours of receiving ADCO LABETALOL
- Raised liver function test.

Less frequent side effects:

- Swelling under the skin
- Slow heart rate, heart block

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO LABETALOL.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store ADCO LABETALOL

Store all medicines out of reach of children.

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

Chemical and physical in-use stability has been demonstrated for up to 24 hours at 2 – 8 °C and at 25 °C when reconstituted diluted with dilution solutions listed in section 6.6 of the PI.

Do not use the medicine after the expiry date on the container.

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6. Contents of the pack and other information

What ADCO LABETALOL contains

The active substance is labetalol hydrochloride; each ml contains 5 mg labetalol hydrochloride.

The other ingredients are: glucose anhydrous, edetate disodium, propylparaben, methylparaben, citric acid monohydrate, sodium hydroxide and water for injection.

What ADCO LABETALOL looks like and contents of the pack

ADCO LABETALOL 5 mg/ml solution for injection (40 ml) is packaged in a 50 ml clear transparent USP Type I moulded glass vial with a 20 mm dark grey bromobutyl rubber stopper sealed with a 20 mm aluminium flip-off seal with coloured button. The immediate container is then placed in a unit carton.

1/5/10 vials may be packed in a carton.

Holder of Certificate of Registration

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