SUMMARY OF PRODUCT CHARACTERISTICS
GALAXY'S LABELOL INJECTION (Labetalol Hydrochloride 5 mg/ml Solution for Injection)

1. NAME OF THE MEDICINAL PRODUCT

GALAXY'S LABELOL INJECTION (Labetalol Hydrochloride 5 mg/ml Solution for Injection)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution for injection contains labetalol hydrochloride 5 mg.

Each 20 ml ampoule contains labetalol hydrochloride 100 mg.

Excipients with known effect:

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LABELOL INJECTION is indicated for the treatment of:

- Severe hypertension, including severe hypertension of pregnancy, when rapid control of blood pressure is essential.
- Anaesthesia when a hypotensive technique is indicated.
- Hypertensive episodes following acute myocardial infarction.

4.2 Posology and method of administration

General

LABELOL INJECTION is intended for intravenous use in hospitalised patients only. The plasma concentrations achieved after intravenous labetalol in severe hypertension are substantially greater than those following oral administration and provide a greater degree of alpha-adrenoceptor blockade necessary to control the more severe disease. Patients should always receive the drug whilst in the supine or left lateral decubitus position. Raising the patient into the upright position within 3 hours of intravenous labetalol administration should be avoided since excessive postural hypotension may occur.

Bolus injection

If it is essential to reduce blood pressure rapidly (e.g. in hypertensive encephalopathy), a dose of 50 mg labetalol hydrochloride should be given by slow intravenous injection over at least 1 minute. If necessary, doses of 50 mg may be repeated at 5-minute intervals until a satisfactory response occurs. The total dose should not exceed 200 mg. The maximum effect usually occurs within 5 minutes of bolus injection; the effective duration of action is usually approximately 6 hours but may be as long as 18 hours.

Intravenous infusion

Dilute the contents of two ampoules (200 mg) to 200 ml with Sodium Chloride and Dextrose Injection BP or 5% Dextrose Intravenous Infusion BP. The resultant infusion solution contains 1 mg/ml labetalol hydrochloride. Administer using a paediatric giving set fitted with a 50 ml graduated burette to facilitate dosage control. Blood pressure and pulse rate should be monitored throughout the infusion.

Hypertension of pregnancy:

Start at 20 mg per hour; the dose may be doubled every 30 minutes until a satisfactory reduction in blood pressure is obtained or a dosage of 160 mg per hour is reached. Occasionally, higher doses may be necessary.

Hypertensive episodes following acute myocardial infarction:

Commence at 15 mg per hour; gradually increase to a maximum of 120 mg per hour depending on blood pressure control.

Hypertension due to other causes:

The rate of infusion should be approximately 2 mg (2 ml of infusion solution) per minute until a satisfactory response is obtained, then the infusion should be stopped. The effective dose is usually 50–200 mg. For most patients it is unnecessary to administer more than 200 mg, but larger doses may be required — especially in patients with phaeochromocytoma.

It is desirable to monitor heart rate throughout the infusion. A small decrease in heart rate is expected; severe bradycardia is unusual but may be controlled with atropine 1–2 mg intravenously. Respiratory function should be observed, particularly in patients with known impairment.

Hypotensive anaesthesia

Induction should be with standard agents (e.g. sodium thiopentone) and anaesthesia maintained with nitrous oxide and oxygen with or without halothane. Recommended starting dose: 10–20 mg IV depending on the age and condition of the patient. Patients for whom halothane is contraindicated usually require a higher initial dose (25–30 mg). If satisfactory hypotension is not achieved after 5 minutes, increments of 5–10 mg should be given until the desired blood pressure is attained.

Halothane and labetalol act synergistically — the halothane concentration should not exceed 1–1.5% as profound falls in blood pressure may be precipitated. Blood pressure can be adjusted by altering the halothane concentration and/or table tilt. The mean duration of hypotension following 20–25 mg labetalol hydrochloride is approximately 50 minutes. Hypotension induced by labetalol is readily reversed by atropine 0.6 mg and discontinuation of halothane.

Once blood pressure is controlled

Maintenance therapy with labetalol tablets should be initiated with a starting dose of one 100 mg tablet twice daily.

Paediatric population

Safety and efficacy have not been established in children.

4.3 Contraindications

- Cardiogenic shock.
- Uncontrolled, incipient or digitalis-refractory heart failure.
- Sick sinus syndrome (including sino-atrial block).
- Second or third degree atrioventricular block.
- Prinzmetal's angina.
- History of wheezing or asthma.
- Untreated phaeochromocytoma.
- Metabolic acidosis.
- Bradycardia (<45–50 bpm).
- Hypotension.
- Hypersensitivity to labetalol or to any of the excipients listed in section 6.1.
- Severe peripheral circulatory disturbances.
- Where peripheral vasoconstriction suggests low cardiac output, use of labetalol to control hypertensive episodes following acute myocardial infarction is contraindicated.

4.4 Special warnings and precautions for use

Postural hypotension

Patients must remain supine or in the left lateral decubitus position during and for at least 3 hours after administration of labetalol injection. Excessive postural hypotension may occur if patients assume an upright position within this period.

Hepatic injury

Rare cases of severe hepatocellular injury have been reported with labetalol therapy; this hepatic injury is usually reversible and has occurred after both short and long-term treatment. Appropriate laboratory testing should be done at the first sign or symptom of liver dysfunction. If there is laboratory evidence of liver injury or the patient is jaundiced, labetalol therapy should be stopped and not restarted.

Cardiac reserve

Due to negative inotropic effects, special care should be taken with patients whose cardiac reserve is poor. Heart failure should be controlled before starting labetalol therapy. Abrupt discontinuation should be avoided in patients with ischaemic heart disease — the dosage should be gradually reduced over 1–2 weeks.

Asthma and obstructive airways disease

Beta-blockers, even those with apparent cardioselectivity, should not be used in patients with asthma or a history of obstructive airways disease unless no alternative is available. If bronchospasm occurs after labetalol use, it can be treated with a beta2-agonist by inhalation (the dose may need to be greater than the usual dose for asthma) and, if necessary, intravenous atropine 1 mg.

Intraoperative floppy iris syndrome (IFIS)

IFIS (a variant of Horner's syndrome) has been observed during cataract surgery in some patients treated with alpha-1-blockers, including labetalol. The ophthalmologist must be informed if the patient is currently receiving or has previously received alpha-1-blocking agents.

Anaesthesia

It is not necessary to discontinue labetalol therapy in patients requiring anaesthesia, but the anaesthetist must be informed. The patient should be given intravenous atropine prior to induction. Labetalol may mask compensatory physiological responses to sudden haemorrhage (tachycardia, vasoconstriction). Anaesthetic agents causing myocardial depression (e.g. cyclopropane, trichloroethylene) should be avoided. Labetalol may enhance the hypotensive effects of halothane. If beta-blockade is interrupted in preparation for surgery, therapy should be discontinued for at least 24 hours.

Bradycardia

Beta-blockers may induce bradycardia. If the pulse rate decreases to less than 50–55 bpm at rest and the patient experiences symptoms, the dosage should be reduced.

Diabetes and hypoglycaemia

Labetalol may mask the tachycardia of hypoglycaemia. Blood glucose should be monitored regularly in diabetic patients. Patients with labile diabetes should be supervised carefully.

Peripheral circulatory disorders

In patients with peripheral circulatory disorders (Raynaud's disease, intermittent claudication), beta-blockers should be used with great caution as aggravation of these disorders may occur.

Psoriasis

Beta-blockers may provoke or exacerbate psoriasis; use only after careful consideration in patients with a history of psoriasis.

Hyperthyroidism

Beta-blockade may mask signs of thyrotoxicosis.

Anaphylactic reactions

Patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge while taking beta-blockers and may be unresponsive to the usual doses of adrenaline (epinephrine) used to treat allergic reactions.

First-degree heart block

Due to a negative effect on conduction time, beta-blockers should only be given with caution to patients with first-degree atrioventricular block.

Laboratory interference

Labetalol interferes with laboratory tests for catecholamines and reduces the uptake of radioisotopes of metaiodobenzylguanidine (MIBG). Labetalol should be withdrawn for at least several days before MIBG scintigraphy and alternative alpha- or beta-blocking drugs substituted.

Sodium content

This medicinal product contains less than 1 mmol sodium (23 mg) per dose and is essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use not recommended

Calcium antagonists (verapamil, diltiazem):

Negative influence on contractility and atrioventricular conduction. Intravenous verapamil must not be co-administered with beta-blockers.

Digitalis glycosides:

Association with beta-blockers may increase atrioventricular conduction time.

Clonidine:

Beta-blockers increase the risk of rebound hypertension upon clonidine withdrawal. When clonidine is used with non-selective beta-blockers, treatment with clonidine should be continued for some time after the beta-blocker has been discontinued.

MAO inhibitors (except MAO-B inhibitors):

Concomitant use is not recommended.

Use with caution

Class I antiarrhythmic agents (disopyramide, quinidine) and amiodarone:

Potentiating effects on atrial conduction time and negative inotropic effect.

Insulin and oral antidiabetic drugs:

Blood glucose-lowering effect may be intensified; beta-blockade may prevent the appearance of signs of hypoglycaemia (tachycardia).

Anaesthetic drugs:

Attenuation of reflex tachycardia and increased risk of hypotension. Agents causing myocardial depression (cyclopropane, trichloroethylene) are best avoided.

Cimetidine, hydralazine and alcohol:

May increase the bioavailability of labetalol.

ACE inhibitors, ARBs, diuretics, alpha-blockers, anxiolytics, hypnotics, aldesleukin, alprostadil, moxisylyte:

May enhance the hypotensive effects of labetalol.

NSAIDs, corticosteroids, oestrogens, progesterones:

May antagonise the hypotensive effects of labetalol.

Dihydropyridine calcium channel antagonists (nifedipine):

Risk of hypotension may be increased. In patients with latent cardiac insufficiency, treatment with beta-blockers may lead to cardiac failure.

Tricyclic antidepressants, barbiturates, phenothiazines, other antihypertensives:

May increase the blood pressure-lowering effect of labetalol. Tricyclic antidepressants may increase the incidence of tremor.

Antimalarials (mefloquine, quinine):

May increase the risk of bradycardia.

Ergot derivatives:

May increase the risk of peripheral vasoconstriction.

Tropisetron:

May increase the risk of ventricular arrhythmia.

Prostaglandin synthetase inhibitors:

May decrease the hypotensive effect of beta-blockers.

Sympathomimetic agents:

May counteract the effect of beta-adrenergic blocking agents.

4.6 Fertility, pregnancy and lactation

Pregnancy

Although no teratogenic effects have been demonstrated in animals, labetalol should only be used during the first trimester of pregnancy if the potential benefit outweighs the potential risk.

Labetalol crosses the placental barrier. Perinatal and neonatal distress (bradycardia, hypotension, respiratory depression, hypoglycaemia, hypothermia) has been rarely reported — sometimes developing a day or two after birth. Response to supportive measures (intravenous fluids and glucose) is usually prompt, but with severe pre-eclampsia — particularly after prolonged intravenous labetalol — recovery may be slower (due to diminished liver metabolism in premature infants).

Beta-blockers reduce placental perfusion, which may result in intrauterine foetal death and premature delivery. There is an increased risk of cardiac and pulmonary complications in the neonate in the post-natal period. Intrauterine and neonatal deaths have been reported with labetalol (in the context of pre-eclampsia, intrauterine growth retardation, prematurity and co-administration of other drugs including vasodilators). Such experience warns against unduly prolonging high-dose labetalol, delaying delivery, and co-administration of hydralazine.

Breast-feeding

Labetalol is excreted in breast milk. Breast-feeding is therefore not recommended during labetalol therapy. Nipple pain and Raynaud's phenomenon of the nipple have been reported.

Fertility

No relevant data available on the effect of labetalol on human fertility.

4.7 Effects on ability to drive and use machines

No studies on the effect of labetalol on the ability to drive have been conducted. Dizziness or fatigue may occasionally occur; patients should be cautioned accordingly.

4.8 Undesirable effects

Summary of the safety profile

LABELOL INJECTION is usually well tolerated. Excessive postural hypotension may occur if patients are allowed to assume an upright position within 3 hours of receiving the injection. Most side-effects are transient and occur during the first few weeks of treatment.

System Organ Class	Adverse Reaction
Blood and lymphatic system disorders	Thrombocytopenia; hyperkalaemia (especially with impaired renal excretion of potassium); positive antinuclear antibody (without disease) (all rare)
Psychiatric disorders	Depressed mood, lethargy, hallucinations, psychoses, confusion, sleep disturbances, nightmares
Nervous system disorders	Headache, tiredness, dizziness; tremor (in treatment of hypertension of pregnancy)
Eye disorders	Impaired vision, dry eyes
Cardiac disorders	Bradycardia, heart block, heart failure, hypotension
Vascular disorders	Ankle oedema, increase of existing intermittent claudication, postural hypotension, cold or cyanotic extremities, Raynaud's phenomenon, paraesthesia of the extremities
Respiratory, thoracic and mediastinal disorders	Bronchospasm (in patients with asthma or history of asthma), nasal congestion, interstitial lung disease
Gastrointestinal disorders	Epigastric pain, nausea, vomiting, diarrhoea
Hepatobiliary disorders	Raised liver function tests, jaundice (hepatocellular and cholestatic), hepatitis, hepatic necrosis
Skin and subcutaneous tissue disorders	Sweating, tingling sensation in the scalp (usually transient, early in treatment), reversible lichenoid rash, exacerbation of psoriasis, systemic lupus erythematosus
Musculoskeletal disorders	Cramps, toxic myopathy
Renal and urinary disorders	Acute retention of urine, difficulty in micturition
Reproductive system and breast disorders	Ejaculatory failure; nipple pain and Raynaud's phenomenon of the nipple (frequency not known)
General disorders	Hypersensitivity (rash, pruritus, angioedema, dyspnoea), drug fever, masking of symptoms of thyrotoxicosis or hypoglycaemia, reversible alopecia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

Bradycardia, hypotension, bronchospasm and acute cardiac insufficiency.

Treatment

Keep the patient under close surveillance in an intensive care setting. Artificial respiration may be required. Bradycardia or extensive vagal reactions should be treated with atropine or methylatropine. Hypotension and shock should be treated with plasma/plasma substitutes and, if necessary, catecholamines. The beta-blocking effect can be counteracted by slow IV isoprenaline hydrochloride (starting dose approximately 5 mcg/min) or dobutamine (starting dose approximately 2.5 mcg/min). If this is insufficient, IV glucagon 8–10 mg may be

considered, repeated within 1 hour if required, followed by IV glucagon infusion at 1–3 mg/hour. Calcium ions or a cardiac pacemaker may also be considered.

Oliguric renal failure has been reported after massive oral labetalol overdose. Haemodialysis removes less than 1% of labetalol hydrochloride from the circulation. Labetalol has membrane-stabilising activity which may have clinical significance in overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alpha and beta blocking agents. ATC code: C07AG01.

Labetalol lowers blood pressure primarily by blocking peripheral arteriolar alpha-adrenoceptors, reducing peripheral resistance, and by concurrent beta-blockade, protects the heart from reflex sympathetic drive that would otherwise occur. The combined alpha- and beta-blockade produces a fall in blood pressure without a compensatory reflex tachycardia.

Cardiac output is not significantly reduced at rest or after moderate exercise. Increases in systolic blood pressure during exercise are reduced, but corresponding changes in diastolic pressure are essentially normal. In patients with angina pectoris co-existing with hypertension, the reduced peripheral resistance decreases myocardial afterload and oxygen demand.

5.2 Pharmacokinetic properties

Plasma half-life of labetalol is approximately 4 hours. Approximately 50% of labetalol in blood is protein-bound. Labetalol is metabolised mainly by conjugation to inactive glucuronide metabolites, which are excreted both in urine and via bile into faeces. Only negligible amounts of the drug cross the blood-brain barrier in animal studies.

5.3 Preclinical safety data

Labetalol Injection has been used in clinical practice for many years and its effects in humans are well known. No additional preclinical safety concerns have been identified beyond those reflected in other sections of this SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrose monohydrate, citric acid monohydrate (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

(Excipient list to be confirmed from approved CTD dossier. Note: Labetalol Injection has been shown to be incompatible with sodium bicarbonate injection BP 4.2% w/v.)

6.2 Incompatibilities

Labetalol Injection has been shown to be incompatible with sodium bicarbonate injection BP 4.2% w/v. Do not mix with other medicinal products except those mentioned in section 4.2.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Protect from light. Store below 30°C. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Type I glass ampoules, 20 ml per ampoule. Pack size: 5 ampoules of 20 ml.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. For dilution instructions, see section 4.2.

7. MARKETING AUTHORISATION HOLDER

GALAXY PHARMACEUTICAL LTD

1st Floor, Doctor's Park, 3rd Parklands Avenue,
P.O. Box 39107-00623, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

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25 Jan 2026

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