# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT
**MYCOGAB GEL**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION :
Gabapentin BP 6% w/w
Lidocaine Hydrochloride BP 5 % w/w
For full list of Excipients, see section 6.1

## 3. PHARMACEUTICAL FORM:
A Clear transparent gel.
Topical gel

## 4. CLINICAL PARTICULARS:
### 4.1 THERAPEUTIC INDICATIONS
Relieving neuropathic pain coming from damaged nerves in variety of different diseases which cause neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes, Cancer, Cancer treatments, multiple sclerosis etc.
It may also be used for certain medical procedures or other neuropathic conditions like Postherpetic neuralgia, Trigeminal neuralgia, Proximal neuropathy, Focal neuropathy as determined by your doctor.

Gabapentin is used with other medications to prevent and control seizures. It is also used to relieve nerve pain following shingles (a painful rash due to herpes zoster infection) in adults. Gabapentin is known as an anticonvulsant or antiepileptic drug.

### 4.2 POSOLOGY AND METHOD OF ADMINISTRATION
The gel should be applied directly to the affected area(s) with a clean finger or small pad of cotton wool. If necessary, applications may be repeated as per the case history.

### 4.3 CONTRAINDICATIONS
This medicine is contraindicated in patients with known allergy to active or any of the excipients listed.

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Do not use or discontinue this medicine if allergic reactions occur, such as rashes

### 4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
***Gabapentin***
i) There are spontaneous and literature case reports of respiratory depression and/or sedation associated with gabapentin and opioid use. In some of these reports, the authors considered this a particular concern with the combination of gabapentin and opioids, especially in elderly patients.
ii) No interaction between gabapentin and phenobarbital, phenytoin, valproic acid, or carbamazepine has been observed.

iii) Gabapentin steady-state pharmacokinetics are similar for healthy subjects and patients with epilepsy receiving these antiepileptic agents.
iv) Coadministration of gabapentin with oral contraceptives containing norethindrone and/or ethinyl estradiol, does not influence the steady-state pharmacokinetics of either component.
v) Coadministration of gabapentin with antacids containing aluminium and magnesium, reduces gabapentin bioavailability up to 24%. It is recommended that gabapentin be taken at the earliest two hours following antacid administration.
vi) Renal excretion of gabapentin is unaltered by probenecid.
vii) A slight decrease in renal excretion of gabapentin that is observed when it is co-administered with cimetidine is not expected to be of clinical importance.

***Lidocaine Hydrochloride***
None stated

**4.6 PREGNANCY AND LACTATION**
Adequate and well-controlled studies on the safety of this medicine during pregnancy and lactation in humans has not been conducted. If necessary, use this medicine, carefully weigh the potential benefits of therapy for the mother and the potential risk to the foetus or infant.
Gabapentin is excreted in breast milk. When this drug used in the lactation period, the character of the action of Gabapentin on the infant is not defined. But it is considered not to constitute a hazard.

**4.7 EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES**
Do not operate heavy machines or do other dangerous activities until you know how Gabapentin affects you. Lidocaine Hydrochloride may no influence, but Gabapentin can slow your thinking and motor skills.

**4.8 UNDESIRABLE EFFECTS**
The undesirable effects associated with this medicinal product are primarily related to **local application site reactions**. These effects are generally **mild to moderate**, **transient**, and resolve spontaneously upon continued use or discontinuation of treatment. Systemic adverse reactions are **unlikely** due to minimal systemic absorption of **gabapentin** and **lidocaine hydrochloride** when applied topically to intact skin; however, they may occur in cases of **excessive use**, **prolonged application**, or **application to damaged skin**.
Adverse reactions are classified according to **system organ class** and **frequency**, using the following convention:

- Very common (≥1/10)
- Common (≥1/100 to <1/10)
- Uncommon (≥1/1,000 to <1/100)
- Rare (≥1/10,000 to <1/1,000)
- Very rare (<1/10,000)
- Not known (cannot be estimated from available data)
- Skin and Subcutaneous Tissue Disorders

**Common:**
Application site irritation, erythema, burning or stinging sensation, tingling, numbness, or transient warmth at the site of application.

**Uncommon:**
Pruritus, rash, dry skin, skin tightness, scaling, or contact dermatitis.
**Rare:**
Urticaria or localized allergic skin reactions.
**Very rare:**
Severe cutaneous hypersensitivity reactions.
**General Disorders and Administration Site Conditions**
**Common:**
Application site discomfort.
**Uncommon:**
Application site swelling, inflammation, or local hypersensitivity reactions.
**Rare:**
Application site pain.
**Immune System Disorders**
**Rare:**
Hypersensitivity reactions.
**Very rare:**
Anaphylactic reactions, particularly in patients with known hypersensitivity to **lidocaine**, other **amide-type local anesthetics**, or any excipients.
**Nervous System Disorders**
Systemic neurological effects are unlikely due to low systemic exposure; however, they may occur following excessive or inappropriate use.
**Uncommon:**
Headache, dizziness.
**Rare:**
Somnolence, paraesthesia occurring distant from the site of application.
**Cardiac Disorders**
**Very rare:**ardiac conduction or rhythm disturbances, associated with excessive systemic exposure to lidocaine.
**Gastrointestinal Disorders**
**Very rare:**
Nausea, particularly following accidental ingestion.

**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 reporting system. This is the national reporting sytem: Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

**4.9 OVERDOSE**
Gabapentin
Symptoms of the overdoses included dizziness, double vision, slurred speech, drowsiness, loss of consciousness, lethargy and mild diarrhea.
Lidocaine Hydrochloride:

The toxic effects of Lidocaine are directly related to blood concentrations. Symptoms are dizziness, fall of blood pressure, muscular tremors, convulsions, coma, irregular and weak breathing, cardiac standstill and bronchospasm. Induced emesis followed by activated charcoal is only useful if the patient is seen within 30 minutes of ingestion. The primary resuscitation aim is airway maintenance. Artificial respiration with oxygen should be given until convulsions or respiratory depression are controlled and blood pressure and pulse return to normal.

## 5. PHARMACOLOGICAL PARTICULARS:

### 5.1 PHARMACODYNAMIC PROPERTIES

***Gabapentin***

**Pharmacotherapeutic group:** Anti-epileptic, Anticonvulsants,

**Mechanism of action:**

Gabapentin readily enters the brain and prevents seizures in a number of animal models of epilepsy. The pharmacological activity of gabapentin may be mediated via binding to α2δ through a reduction in release of excitatory neurotransmitters in regions of the central nervous system, such activity may underlie gabapentin's anti-seizure activity.

It works by functioning in the production of a compound called myelin, which covers and protect nerve fibers. Methylcobalamin rejuvenates the damaged neuron. Without enough methylcobalamin, myelin sheath does not form properly due to which nerve fibers suffers and people experience irreversible nerve damage. An intrinsic factor made in the stomach, must be present in the intestinal tract to allow its proper absorption. People lacking this factor show vitamin B12 deficiencies such as pernicious anemia (a slow and insidious process that can end in death. Pernicious anemia in fact means ‘leading to death’). Methylcobalamin is used as a cofactor in methionine transferase enzyme, an enzyme which converts amino acid homocysteine to methionine via folate cycle

***Lidocaine Hydrochloride***

**Pharmacotherapeutic group:** Topical Anaesthetic

**Mechanism of action:**

It produces more prompt, more intense, longer lasting and more extensive anaesthesia than does an equal concentration of procaine (Peak anaesthesia within 2-5 minutes). Local anaesthetics are drugs that block nerve conduction when applied locally to nerve tissue in appropriate concentrations. They have good powers of penetration and their action is reversible. Their use is followed by complete recovery in nerve function with no evidence of structural damage to nerve fibres or cells.

Aminacrine Hydrochloride is a slow acting disinfectant. It exerts germicidal action against bacteria and fungi. It is used as a surgical and endodontic irrigant and to treat local infections of the ear, mouth and throat. Its exact mode of action is not known but it involves disruption of certain metabolic pathways.

### 5.2 PHARMACOKINETIC PROPERTIES

***Gabapentin***

**Absorption**

Following oral administration, peak plasma gabapentin concentrations are observed within 2 to 3 hours.

Gabapentin bioavailability (fraction of dose absorbed) tends to decrease with increasing dose. Absolute bioavailability of a 300mg capsule is approximately 60%. Food, including a high-fat diet, has no clinically significant effect on gabapentin pharmacokinetics.

**Distribution**

Gabapentin is not bound to plasma proteins and has a volume of distribution equal to 57.7 litres. In patients with epilepsy, gabapentin concentrations in cerebrospinal fluid (CSF) are approximately 20% of corresponding steady-state trough plasma concentrations. Gabapentin is present in the breast milk of breast-feeding women.

**Biotransformation**

There is no evidence of gabapentin metabolism in humans. Gabapentin does not induce hepatic mixed function oxidase enzymes ***responsible*** for drug metabolism.

**Elimination**

Gabapentin is eliminated unchanged solely by renal excretion. The elimination half-life of gabapentin is independent of dose and averages 5 to 7 hours.

In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced.

***Lidocaine Hydrochloride***

Lignocaine is readily absorbed through mucous membranes. They exert their effects in the form of the non-ionised base. Lignocaine undergoes first-pass metabolism in the liver and bioavailability is low after administration by mouth.

It is rapidly de-ethylated to the active metabolite monoethyl glycinexylidide and then hydrolysed by amidases to various compounds, including glycineexylidide which has reduced activity but a longer elimination half-life. Less than 10% of a dose is excreted unchanged via the kidneys. The metabolic products are excreted in the urine.

**5.3 PRECLINICAL SAFETY DATA**

Not applicable

**6. PHARMACEUTICAL PARTICULARS**

**6.1 LIST OF EXCIPIENTS**

Methyl hydroxy benzoate
Propyl hydroxy benzoate
Disodium Edetate
Propylene glycol,
Carbomer
Isopropyl alcohol
Triethanolamine
Purified water

**6.2 INCOMPATIBILITIES:**

None such data reported

**6.3 SHELF-LIFE:**

24 months

**6.4 SPECIAL PRECAUTIONS FOR STORAGE:**

Store below 30°C. Protected from light.

**6.5 NATURE AND CONTENTS OF CONTAINER:**
30gm Lami Tube

**6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:**
Any unused product or waste material should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES: --**

**MARKETING AUTHORIZATION HOLDER:**
**GALAXY PHARMACEUTICAL LTD**
P.O. Box 39107-00623, Nairobi, Kenya

**MANUFACTURING SITE ADDRESS:**
FREDUN PHARMACEUTICALS LTD.
14, 15, 16, Zorabian lndustrial Complex,
Vevoor, Palghar(E)-401 404.INDIA

**8. MARKETING AUTHORIZATION NUMBER:**
**CTD8746**

**9. DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION:**
**14/07/2026**

**10. DATE OF REVISION OF TEXT:**
**14/07/2026**