

## Trade Name:

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Ultracaine gel

## Composition:

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Each gm gel contains:

Lidocaine (base)            50 mg

## Pharmacological properties:

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Ultracaine gel is an amide – type local anaesthetic agent which stabilizes neuronal membranes by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anaesthetic action.

## Pharmacokinetics:

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The amount of Lidocaine systemically absorbed from ultracaine gel is directly related to both the duration of application and to the area over which it is applied.

Lidocaine is metabolized rapidly by the liver to a number of metabolites that have pharmacologic activity similar to, but less potent than that of Lidocaine.

## Indications:

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Ultracaine gel is indicated for temporary relief of pain associated with minor cuts and abrasions of the skin, minor burns, including sunburn, minor skin irritation, insect bites, local discomfort including pain and itching, soreness or burning associated with anorectal diseases and haemorrhoids.

## Contraindications:

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Ultracaine gel is contraindicated in patients with a known history of sensitivity to local anaesthetics of the amide type or to any other component of the product.

## Precautions:

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Ultracaine gel can be absorbed through the rectal mucosa; therefore excessive application should be avoided, particularly in infants and children.

Ultracaine gel should be used with caution in patients who are sensitive to the systemic effects of lidocaine as acutely ill, debilitated or elderly patients.

Caution should be exercised, when applying Ultracaine gel over large areas and leaving it on for longer than 2 hours.

### **Pregnancy:**

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Ultracaine gel should be used during pregnancy only if clearly needed.

### **Lactation:**

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Caution should be exercised when Ultracaine gel is administered to a nursing mother since lidocaine is excreted in human milk.

### **Warnings:**

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- Ultracaine gel is for external use only, avoid contact with eyes.
- Don't apply to irritated skin or if excessive irritation develops.
- If condition persists for seven days or clears up and occurs again within only few days, discontinue use and consult a doctor.
- Don't apply to raw or blistered areas.
- Application of Ultracaine gel to larger areas or for longer times than those recommended could result in sufficient absorption of lidocaine resulting in serious adverse effects.

### **Side effects:**

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- Localized reactions: During or immediately after treatment with Ultracaine gel, the skin at the site of treatment may develop erythema or edema.
- Allergic reactions with Ultracaine gel can occur.

### **Drug interactions:**

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Ultracaine gel should be used with caution in patients receiving class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and generally synergistic.

### **Overdosage:**

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Peak blood levels following a 60 gm application to 400 cm<sup>2</sup> for 3 hours are 0.05 to 0.16 µg/ml for lidocaine. Toxic levels of lidocaine (>5µg/ml) cause decreases in cardiac output, total peripheral resistance and mean arterial pressure.

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## Dosage and administration:

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Apply a layer of Ultracaine gel to intact skin or as directed by the physician.

## Therapeutic category:

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Local anaesthetic.

## Legal category:

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OTC.

## Storage :

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Store at a temperature below 30°C.

## Package:

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Tubes each containing 20gm gel.

### ***THIS IS A MEDICAMENT***

*Medicament is a product ,which affects your health and its consumption contrary to instructions is dangerous for you .*

*Follow strictly the doctor's prescription ,the method of use and the instructions of the pharmacist who sold the medicament .*

- *The doctor and the pharmacist are the experts in medicines ,their benefits and risks .*
- *Do not by yourself interrupt the period of treatment prescribed .*
- *Do not repeat the same prescription without consulting your doctor .*
- *Keep all medicaments out of reach of children .*

*Council of Arab Health Ministers ,Union of Arab Pharmacists .*