

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

STUD 100
Desensitizing Spray for Men

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

STUD 100 contains Lidocaine Base USP 9.6% w/w as the active ingredient.

3. PHARMACEUTICAL FORM

Cutaneous spray, solution (cutaneous spray).

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

To reduce tactile sensitivity of the penis in advance of intercourse as a means of delaying ejaculation in cases of over-rapid or precipitant ejaculation.

4.2 Posology and Method of Administration

Adults 3-8 sprays (23-62 mg lidocaine base) applied to the glans and shaft of the penis 5 to 15 minutes prior to intercourse.

Quantity and advance timing will be determined by individual requirements. The minimum effective dose should be used.

The maximum dose should not exceed 24 sprays (186 mg lidocaine base) in 24 hours. The product should not be used repeatedly for more than 3 months without medical supervision

Children: Not applicable

Elderly: Not recommended

4.3 Contra-Indications

Known hypersensitivity to amide type local anaesthetics.

4.4 Special Warnings and Precautions for Use

Discontinue use if a rash or irritation develops.

If symptoms persist consult a doctor.

Wash off after intercourse.

Do not spray in eyes or nostrils.

For external use only.

If you have liver or kidney failure, consult your doctor before using this product.

Keep medicines away from children.

4.5 Interaction with other Medicaments and other forms of Interaction

Reports of interactions have been associated generally with systemic administration of lidocaine which results in high blood concentrations. The systemic uptake of lidocaine from STUD 100 is unlikely to be sufficient to produce interactions.

Interactions have been reported with antiarrhythmic agents, anticonvulsants, anticholinergic agents, antihypertensives, barbiturates, beta-blockers, muscle relaxants and sympathomimetic agents. Interactions with diagnostic tests for serum enzymes have also been reported.

4.6 Pregnancy and Lactation

STUD 100 is only indicated for use in males. However, possible transfer of lidocaine to the female partner could occur during intercourse. Whilst there is no, or inadequate, evidence of safety of lidocaine in human pregnancy, it has been in widespread use without apparent adverse effects. Animal studies have shown no hazard.

At the proposed male dose, the systemic availability of lidocaine to the female partner is unlikely to result in any adverse effects.

Use of STUD 100 should be avoided if the female is pregnant.

4.7 Effects on Ability to Drive and Use Machines

The systemic uptake of lidocaine from STUD 100, applied topically, is unlikely to result in plasma concentrations sufficient to impair the ability to drive or operate machinery.

4.8 Undesirable Effects

In extremely rare cases local anaesthetic preparations have been associated with allergic reactions. Occasional local skin irritation may occur following the use of STUD 100.

Systemic adverse reactions to lidocaine are usually the result of high plasma concentrations due to high dosage, rapid absorption or may result from hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Such reactions involve excitatory and/or depressant actions on the CNS characterised by nervousness, dizziness, convulsions, unconsciousness and possible respiratory arrest. Cardiovascular reactions are depressant and may include hypotension, myocardial depression, bradycardia and possibly cardiac arrest.

The plasma lidocaine levels attained following application of STUD 100 at the maximum recommended dose are extremely low at about 25 times lower than the concentrations associated with systemic toxicity.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

([@moh.gov.il](http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic)).

4.9 Overdose

Overdose of lidocaine with STUD 100 is unlikely due to the small container size and low systemic availability of lidocaine following topical application. Signs of overdosage of lidocaine include stimulation and/or depression of the CNS. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Lidocaine is a local anaesthetic, of the amide type, the effects of which are reversible. Lidocaine is also a Class 1A antiarrhythmic agent. It acts by preventing generation and transmission of impulses along nerve fibres and at nerve endings. It blocks nerve conduction by decreasing or preventing the large transient increase in the permeability of the cell membrane to sodium ions which is produced by a slight depolarisation of the membrane. The main site of action is the cell membrane. The local anaesthetic properties of lidocaine therefore form the basis for the use of STUD 100 in reducing tactile sensitivity of the penis.

5.2 Pharmacokinetic Properties

Lidocaine is readily absorbed from the gastrointestinal tract, from mucous membranes, and through damaged skin. Lidocaine is rapidly distributed into the heart, brain, kidneys and other tissues with a high blood flow. It diffuses across the placenta a few minutes after injection.

Lidocaine undergoes first-pass metabolism in the liver and bioavailability is low after administration by mouth. It is rapidly de-ethylated to the active metabolite monoethylglycinexylidide and then hydrolysed by amidases to various compounds, including glycinexylidide which has reduced activity but a longer elimination half-life and may accumulate to potentially toxic concentrations. Less than 10% of a dose is excreted unchanged via the kidneys. The metabolic products are excreted in the urine.

Systemic availability of lidocaine is low following application to intact skin. After application of STUD 100 to the penis at the maximum recommended dose, plasma lidocaine levels were in the region of 0.2µg/ml with peak concentrations attained 1-2 hours after application.

5.3 Preclinical Safety Data

No new data presented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Isopropyl Myristate BP
2-(2-Ethoxyethoxy)ethanol
Stearic Acid BP
Perfume 120

6.2 Incompatibilities

None known.

6.3 Shelf-life

Five (5) years.

6.4 Special Precautions for Storage

Store up to 25°C.

6.5 Nature and Contents of Container

Internally lacquered aluminium can with metered pump spray and aluminium cap, containing 12g STUD 100 Desensitizing Spray for Men.

6.6 Instructions for Use/Handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

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