# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

STUD 100 Desensitizing Spray for Men

Premjact Desensitizing Spray for Men

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

STUD 100 contains Lidocaine 9.6% w/w as the active ingredient (7.7 mg per metered spray).

Excipient with known effect:

STUD 100 contains fragrance with benzyl cinnamate, butylated hydroxytoluene, citral, hexyl cinnamaldehyde and tree moss.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous spray, solution (cutaneous spray).

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

To reduce tactile sensitivity of the penis in adults 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 (185 mg lidocaine base) in 24 hours.

The product should be washed off after intercourse.

Do not use on broken or inflamed skin.

Do not spray in eyes or nostrils.

For external use only.

The product should not be used repeatedly for more than 3 months without medical supervision.

There is no relevant use of STUD 100 in the paediatric population.

Elderly: Not recommended.

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

## 4.4 Special warnings and precautions for use

Use should be discontinued if a rash or irritation develops.

A doctor should be consulted if symptoms persist.

Although this topical formulation with limited systemic availability is unlikely to have a clinically meaningful effect on hepatic or renal function, caution is advised prior to prescribing to patients with hepatic or renal failure.

The fragrance components benzyl cinnamate, citral, hexyl cinnamaldehyde and tree moss may cause allergic reactions. In addition to allergic reactions in sensitised patients, non-sensitised patients may become sensitised.

Butylated hydroxytoluene may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## 4.5 Interaction with other medicinal products 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.

## 4.6 Fertility, 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.

Patients planning a pregnancy should either avoid using STUD 100 or wash it off thoroughly just prior to intercourse.

## 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 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 (see details below).

United Kingdom

Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

## 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 include stimulation and/or depression of the CNS. Treatment is symptomatic.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: local anaesthetics, amides.

ATC code: N01BB02

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

Absorption

Lidocaine is readily absorbed from the gastrointestinal tract, from mucous membranes, and through damaged skin.

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 0.2 µg/ml with peak concentrations attained 1-2 hours after application.

Distribution

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.

Biotransformation

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.

Elimination

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

No new data presented.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Isopropyl myristate

Diethylene glycol monoethyl ether

Stearic acid

Perfume Masculine 120

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Five (5) years

### 6.4 Special precautions for storage

Store below 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 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Pound International Ltd

Castle Keep

High Street

Deddington

Oxfordshire

OX15 0SJ United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 02294/5000R

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 October 1972

Date of latest renewal: 07 October 2002

## 10 DATE OF REVISION OF THE TEXT

03/12/2024