SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

MEDIJEL GEL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride BP	0.66% w/w
Aminoacridine Hydrochloride BP 1968	0.05% w/w

3 PHARMACEUTICAL FORM

Oral Gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The quick, effective relief from the pain of common mouth ulcers and denture rubbing. Medijel Gel is administered directly onto the affected area with a clean finger or small pad of cotton wool.

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 application may be repeated after 20 minutes.

Each dose is approximately 300mg, i.e. 2mg of Lidocaine Hydrochloride and 0.15mg of Aminoacridine Hydrochloride.

Medijel Gel can be used as directed for adults and children.

4.3 Contraindications

Hypersensitivity to the active substances or to any other of the ingredients.

Contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

If symptoms persist longer than 7 days following the use of the product a doctor or dentist should be consulted. Not suitable for treatment of teething in children.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

The safety of Medijel Gel during pregnancy and lactation has not been established, but is considered not to constitute a hazard.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse effects at therapeutic doses are usually mild and transient
Hypersensitivity reactions to Lidocaine have been reported on rare occasions.

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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Maximum safe dosage for a 70kg adult is 750mg for Lidocaine (Goodman & Gilman, page 313). The Lidocaine hydrochloride content of a 15g tube of Medijel Gel is 99mg- therefore overdose is not a problem.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lidocaine Hydrochloride is well documented in Martindale 28th Edition Page 900-904 and Goodman & Gilman, Chapter 15 and pages 767-770.

Lidocaine Hydrochloride was first introduced in 1948 and is one of the most widely used local anaesthetics, producing 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.

Aminoacridine Hydrochloride is a slow acting disinfectant. It exerts germicidal action against bacteria and fungi. It is also 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

Lidocaine is readily absorbed through mucous membranes. They exert their effects in the form of the non-ionised base. 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 anuidases 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.

Aminoacridine Hydrochloride if administered systematically is rapidly eliminated through the kidney (0.2 grams being eliminated from the blood in 30 minutes). (Medijel Gel dose 0.15mg Aminoacridine hydrochloride).

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol, Hydroxypolyethoxydodecane HSE, Alcohol 96% v/v, Carbomer, Sucrose, Saccharin Sodium, Peppermint Oil, Ethyl vanillin, Di-isopropanolaniine 90% aqueous, Purified Water.

6.2 Incompatibilities

None encountered

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tube with membrane seal and spiked polyethylene cap.
Pack size: 15g.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Dendron Brands Limited
94, Rickmansworth Road
Watford
Hertfordshire
WD18 7JJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 52731/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/05/2003

10 DATE OF REVISION OF THE TEXT

16/11/2020