

## PATIENT INFORMATION LEAFLET

# Xylonor 50 mg/ 1.5 mg per gram Gingival Gel

## Lidocaine / Cetrимide

### Read all this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours
- The active substances are: lidocaine 50 mg per gram and cetrимide 1.5 mg per gram
- The other ingredients are: saccharin, natural mint flavour (contains spearmint oil and eucalyptus oil), macrogol 4000, macrogol 1500, macrogol 300

### Marketing Authorisation Holder and Manufacturer:

SEPTODONT

58, rue du Pont de Créteil - 94100 Saint-Maur-des-Fossés - France

## WHAT XYLONOR GEL IS AND WHAT IT IS USED FOR

Local anaesthetic.

Gingival gel, white to ivory translucent with a mint odour.

Xylonor Gel contains lidocaine, an anaesthetic agent which stabilises the neuronal membrane and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthesia. Cetrимide is an antiseptic of the quaternary ammonium group with both bactericidal and detergent properties.

Xylonor Gel allows a topical anaesthesia in the buccal cavity.

Xylonor Gel is packaged in aluminium tubes internally coated with epoxy varnish, with a polyethylene screw cap.

The marketing presentation is a tube containing 15 g of gel.

Xylonor Gel is used for production of topical anaesthesia in the buccal cavity.

## BEFORE YOU USE XYLONOR GEL

- Do not use Xylonor Gel
  - If the gel does not appear white to ivory translucent, with a mint odour or seems deteriorated
  - If you are hypersensitive (allergic) to lidocaine and/or cetrимide or to any of the other ingredients of the product
- Take special care with Xylonor Gel
  - In debilitated, elderly patients, acutely ill patients and children. In these cases, reduced doses should be given, commensurate with the age and the physical status of the patient
  - If there is sepsis or extremely traumatised mucosa in the area of application
  - In persons with known drug sensitivities
  - If the patient is a child under 3 years old

### Interactions with food and drink:

In order to avoid burns, it is recommended not to drink or eat hot food until effects of Xylonor Gel have worn off.

### Pregnancy

The administration to pregnant women should be carried out with caution.

**Ask your doctor or pharmacist for advice before using any medicine.**

### Breast-feeding

Because of the lack of studies relating to the excretion in human milk, the administration should be carried out with caution.

**Ask your doctor or pharmacist for advice before using any medicine.**

### Driving and using machines

Because of the used doses, adverse effects are unlikely.

### Using other medicines

**Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.**

- soaps and anionic surfactants known to decrease the bactericidal

activity of cetrимide

- Other local anaesthetics or antiarrhythmic drugs
- Beta-adrenergic blocking agents which may slow metabolism of lidocaine because of decreased hepatic blood flow
- Cimetidine (drugs against stomach ulcer) which may inhibit hepatic metabolism of lidocaine

## HOW TO USE XYLONOR GEL

**Always use Xylonor Gel exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.**

The physicians or dentists are only authorised to use Xylonor Gel because they are trained in local anaesthesia techniques and their complications.

Only one dose (from 0.1 - 0.5 g gel) must be used. In one session, 4 g of gel must not be exceeded.

However, your doctor or dentist may decide to administer a smaller or greater amount of Xylonor Gel. He will adjust the posology according to your age, weight, health condition and to the surface to be anaesthetised.

Do not use in children under 3 years of age.

If you have the impression that the effect of Xylonor Gel is too strong or too weak, talk to your doctor or pharmacist.

If the physician or dentist use more Xylonor Gel than they should, symptoms of overdose can appear:

- *Central Nervous System manifestations:* nervousness, dizziness, blurred vision and tremors, followed by drowsiness, convulsions, unconsciousness and possibly respiratory arrest
- *Cardiovascular manifestations:* hypotension, myocardial depression, bradycardia and possibly cardiac arrest

### Instructions:

- Assuring and maintaining a patent airway
- Supporting ventilation with oxygen
- Assisted or controlled ventilation as required
- Should a convulsion persist despite ventilatory therapy, small increments of anticonvulsive agents may be given intravenously:
  - benzodiazepine (e.g., Diazepam)
  - ultrashort acting barbiturates (e.g., Thiopental or Thiamylal)
  - short acting barbiturates (e.g., Pentobarbital, Secobarbital)
- Cardiovascular depression may require circulatory assistance with intravenous fluids and/or vasopressors (e.g., Ephedrine)

## POSSIBLE SIDE EFFECTS

Like all medicines, Xylonor Gel can have side effects.

Nervous manifestations: nervousness, dizziness, blurred vision, tremors, drowsiness, convulsions, unconsciousness, respiratory arrest.

Cardiovascular manifestations: slowing of the heart rate, hypotension, myocardial depression, cardiac arrest.

General manifestations: allergic reactions characterised by cutaneous lesions, urticaria and oedema.

**If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.**

## STORING XYLONOR GEL

Keep out of the reach and sight of children.

Do not store above 25°C.

Keep the tube tightly closed.

Do not use Xylonor Gel after the expiry date which is stated on the label, the carton and the tube.

## FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the marketing authorisation holder.

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