

**OPINION ON
MEDICINAL
PRODUCTS**

lidocaine

GLYDO 20 mg/mL,

gel in prefilled syringe

First assessment

Adopted by the Transparency Committee on 14 December 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of reimbursement for local contact anaesthesia and lubrication for cystoscopy, catheterisation, instrumental investigation procedures and other endourethral procedures for adult and adolescent male and female patients only.

Disapproval of reimbursement for other marketing authorisation indications.

Therapeutic improvement?

No therapeutic improvement in relation to other lidocaine-based proprietary urethral gel medicinal products already listed (XYLOCAINE 2% (lidocaine), urethral gel in prefilled syringe).

Role in therapeutic strategy?

→ Local anaesthesia for cystoscopy, catheterisation, instrumental investigation and other endourethral procedures

Based on expert opinion, most urological investigations are performed without sedation or general anaesthesia and on an outpatient basis. For this type of endoscopic procedure, sterile aqueous gel must be used. However, some endourethral procedures may be unpleasant, such as patients who need to perform urinary self-catheterisation (particularly for men).

Given that pain management is a key concern for interventional practitioners, the use of an anaesthetic and lubricant gel may also be proposed when the procedure is painful.

For children:

- cystoscopy is performed under general anaesthesia
- bladder catheterisation may be performed for a urinary cytobacteriology test or to carry out cystography to detect vesicoureteral reflux and in the event of an abnormality detected by ultrasound. In these cases, it is recommended to use a lubricant.

Role of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe in the therapeutic strategy:

Introducing a new lidocaine-based proprietary medicinal product is not likely to modify the Committee's opinion on other lidocaine-based proprietary medicinal products (in urethral gel already available) used prior to urological investigation (XYLOCAINE 2% (lidocaine), urethral gel in prefilled syringe) in adults and adolescents.

It is a first-line treatment for preventive pain management in urological investigations.

As mentioned in the summary of product characteristics, the Committee points out the importance of waiting at least 5 minutes before conducting urological examinations in order to obtain suitable local anaesthesia. The anaesthesia lasts for approximately 20 to 30 minutes.

For children (2 to 11 years), the effect of lidocaine hydrochloride monohydrate gels is not clearly documented and demonstrated. The systemic uptake of lidocaine may be increased and caution is therefore required. As such, lidocaine in urethral gel form has no role for children prior to a urological investigation procedure.

→ Local anaesthesia for rectoscopy

Rectoscopy is preceded by a digital anorectal examination enabling lubrication, and the apparatuses are then introduced into the anus after having been lubricated themselves. In routine practice, based on expert opinion, lubrication is provided by water-based lubricant gels (such as KY).

Role of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe in the therapeutic strategy:

Considering the lack of clinical data and specific guidelines, GLYDO 20 mg/mL (lidocaine), sterile gel in prefilled syringe has no role for rectoscopy.

→ Symptomatic treatment of pain associated with chronic interstitial cystitis

Painful bladder syndrome is difficult to manage. Analgesics, antispasmodics, non-steroidal anti-inflammatories/NSAIDs with a proton pump inhibitor/PPI are generally ineffective. A number of medicinal products are used off-label via the oral or parenteral route: tricyclic antidepressants (amitriptyline hydrochloride) and antihistamines (hydroxyzine) may be effective.

The proprietary medicinal product ELMIRON (pentosan sodium) 100 mg capsules is indicated for the treatment of painful bladder syndrome characterised in particular by Hunner ulcers in adults suffering from moderate to severe pain, urgency of urination and pollakiuria.

After failure to respond to oral painful bladder syndrome treatments, the 2022 European Association of Urology (EAU) **Erreur ! Signet non défini.** guidelines recommend:

- intravesical instillations of local anaesthetics, hyaluronic acid, chondroitin sulphate and heparin (off-label use) before setting up more invasive measures. Lidocaine has been proposed by the intravesical route to improve bladder symptoms; dimethylsulphoxide (DMSO) in bladder installations has also been used; botulinum toxin injections into the bladder have also been proposed.
- hydrodistention may provide relief for patients, but requires general anaesthesia.
- in the event of Hunner ulcers, electrocoagulation or preferably ulcer resection is recommended.

Surgery (TENS / subcutaneous sacral implant, augmentation enterocystoplasty, cystectomy, sacral root denervation, etc.) must be envisaged, as a last resort, if all other treatments have failed and the symptoms become extremely incapacitating.

Role of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe in the therapeutic strategy:

Considering the low level of evidence of the clinical data available, GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe has no role in symptomatic treatment of pain associated with chronic interstitial cystitis.

Committee's conclusions

Clinical Benefit

Local anaesthesia for cystoscopy, catheterisation, instrumental investigation and other endourethral procedures

- ➔ Urological investigation procedures are painful examinations.
- ➔ The proprietary medicinal product GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is a symptomatic medicinal product.
- ➔ Despite the heterogeneity of the data from the studies available, given the well-established medical use, the efficacy/adverse effect ratio is significant as XYLOCAINE 2% (lidocaine), urethral gel in prefilled syringe but only for adults and adolescents. For children, on account of the lack of robust evidence and the risk of an increase in systemic uptake of lidocaine, the efficacy/adverse effect ratio is poorly defined.
- ➔ An alternative is available based on lidocaine alone in urethral gel form, XYLOCAINE 2% (lidocaine), urethral gel in prefilled syringe.
GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is a therapeutic alternative. It is a first-line treatment for adults and adolescents.

➔ Public health benefit

GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is not likely to have an additional impact on public health.

Considering all of these elements, for local contact anaesthesia and lubrication for cystoscopy, catheterisation, instrumental investigation procedures and other endourethral procedures in male and female patients, the Committee deems that that actual clinical benefit of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is:

- significant from 12 years of age;
- insufficient for children under 12 years of age to justify public funding in view of the alternatives available.

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for local contact anaesthesia and lubrication during cystoscopy, catheterisation, instrumental investigation procedures and other endourethral procedures in male and female patients, only, from 12 years of age and at the marketing authorisation dosages.

Recommended reimbursement rate: 65%

Local anaesthesia for rectoscopy

- Rectoscopy procedures are non-painful examinations.
- The proprietary medicinal product GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is a symptomatic medicinal product.
- Considering the lack of data on efficacy and the lack of guideline in force, the efficacy/adverse effect ratio is poorly defined.
- Water-based lubricant gels, used during these examinations, provide alternatives.
- This proprietary medicinal product has no role in this indication.

→ Public health benefit

Considering:

- the severity of the disease,
- the low prevalence,
- the lack of medical need for sterile medicinal products in this clinical context,
- the lack of data and guidelines in this indication,
- the lack of evidence of an additional impact on the care or life pathway,

GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is insufficient for local contact anaesthesia and lubrication in rectoscopy, to justify public funding in view of the alternatives available.

The Committee disapproves inclusion in proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for local contact anaesthesia and lubrication in rectoscopy and at the marketing authorisation dosages.

Symptomatic treatment of pain associated with chronic interstitial cystitis

- Painful bladder syndrome is a rare chronic disease, with the onset of symptoms potentially impacting everyday activities and impairing quality of life.
- The proprietary medicinal product GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is a symptomatic medicinal product.
- Considering the lack of evidence of efficacy with a robust level of evidence, the efficacy/adverse effect ratio is poorly defined.
- The alternatives are intravesical instillations of hyaluronic acid, chondroitin sulphate and heparin, used off-label, cited in European guidelines.
- This proprietary medicinal product has no role in this indication.

→ Public health benefit

Considering:

- the rare nature of the disease,
- the possible onset of symptoms impacting everyday activities and impairing quality of life,
- the unmet medical need,
- the lack of response to the identified need with robust evidence of efficacy,
- an effect on quality of life that has yet to be demonstrated.

GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of GLYDO 20 mg/mL (lidocaine), gel in prefilled syringe is insufficient for the symptomatic treatment of pain associated with cystitis, to justify public funding in view of the alternatives available.

The Committee disapproves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the symptomatic treatment of pain associated with cystitis and at the marketing authorisation dosages.

Clinical Added Value

Considering:

- the well-established medical use of lidocaine by the urethral route in local contact anaesthesia prior to urological investigation;
- the need met by another proprietary urethral gel medicinal product, based on lidocaine alone,
- the heterogeneity of the findings of the clinical studies available according to the urological procedure, sex and age;

the Committee deems that this proprietary medicinal product provides no clinical added value (CAV V) in relation to the lidocaine-based proprietary urethral gel medicinal products already listed.

GLYDO 20 mg/mL, 14 December 2022
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