Medicines Adverse Reactions Committee

Meeting date	**11/06/2020**	Agenda item	3.1.1
Title	**Consideration of Cathejell (lignocaine) 2% Gel under section 36 of the Medicines Act 1981**		
Submitted by	Medsafe Compliance Team	Paper type	For advice
Active ingredient	**Product name**	**Sponsor**	
Lignocaine 2% Gel	Cathejell	KSJ Pharmatech Limited	
PHARMAC funding	Not funded		
Previous MARC meetings	Cathejell (lignocaine) 2% gel has not been previously discussed by MARC		
Prescriber Update	Monitoring Communication= published on the Medsafe website 19 August 2019. https://medsafe.govt.nz/safety/Alerts/Cathejell.asp		
Classification	Pharmacy-only medicine		
Usage data	[redacted]		
Advice sought	**The Committee is asked to advise whether:** • The balance of benefit and patient risk for the use of Cathejell (lignocaine) 2% gel (Lignocaine 2% Gel) for use as a surface anaesthetic and lubrication for catheterisation (and other approved uses, see section 2.4). • Any regulatory action is required to improve the balance of benefits and patient safety risk.		

Table of Contents

1. **PURPOSE**

The purpose of this paper is to review the information provided by Montavit (the company) in response to the section 36 notice.

2. BACKGROUND

In June 2019 it was announced that PHARMAC were to award sole subsidy to Cathejell (lignocaine) 2% gel from November 2019. Prior to this time a different product was funded, Lignocaine 2% gel, by Pfizer New Zealand Limited. Following this decision Medsafe received notification from [redacted] expressing their concerns with Cathejell (lignocaine) 2% gel. The DHB's outlined issues associated with the use of Cathejell (lignocaine) 2% gel, including:

- A rough edge at the top of the applicator that is uncomfortable for patients and could cause harm.
- Pain on insertion as the user found it difficult to create sufficient pressure to release the gel on insertion.
- The gel was painful causing a 'stinging' sensation.
- During insertion air bubbles can be introduced and there is potential to create a vacuum immediately following insertion.
- It is easy to spill the product, potentially resulting in an incomplete dose.
- The product requires training to ensure safe use, which is not currently available.

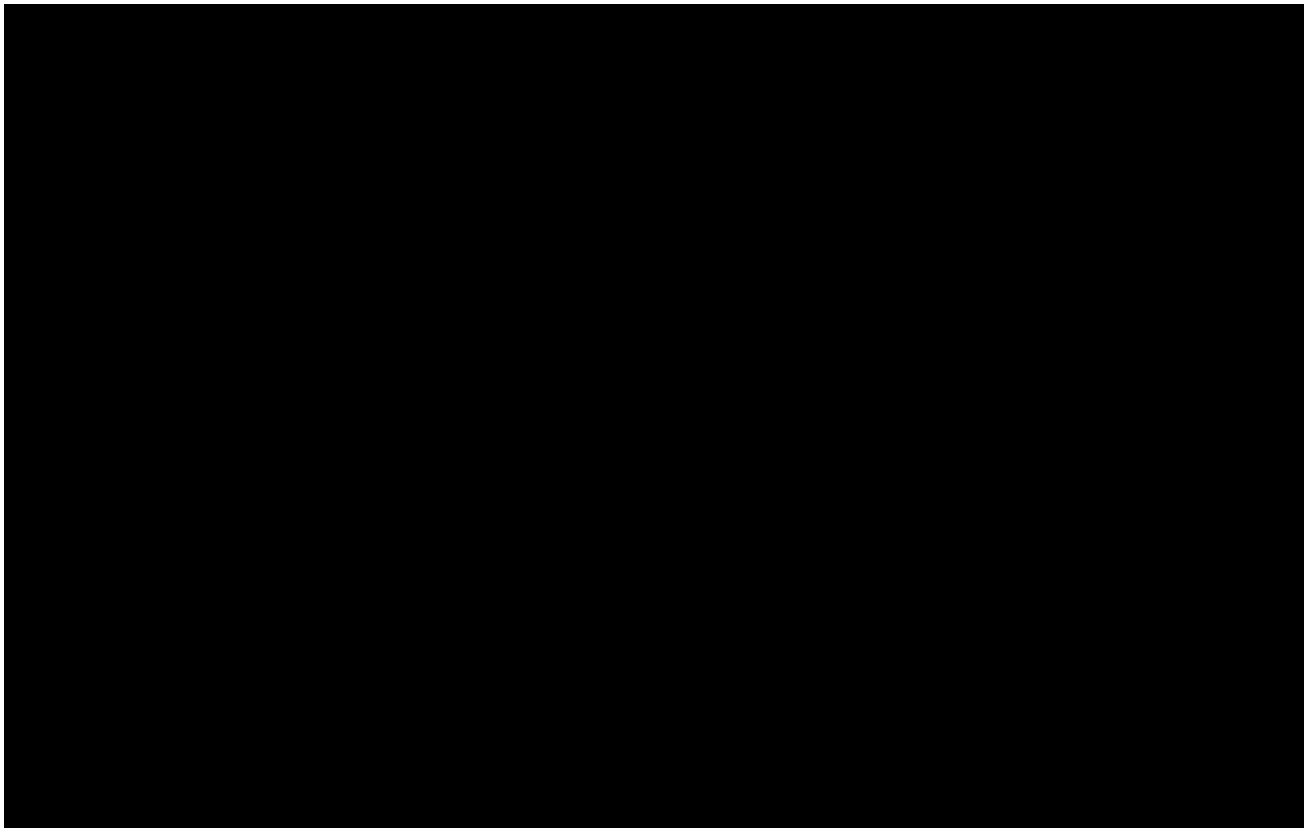
The New Zealand sponsor for Cathejell (lignocaine) 2% gel at the time, Healthcare Logistics NZ Limited, were issued with a notice given under section 36 of the Medicines Act 1981 regarding Cathejell (lignocaine) 2% gel on 19 November 2019 outlining the reported safety concerns.

Comments:
As at 1 April 2020 Cathejell (lignocaine) 2% gel has been removed from the PHARMAC schedule, and Instillagel Lido (lignocaine) 2% gel has sole subsidised supply. Instillagel Lido (lignocaine) 2% gel is an approved medicine New Zealand and the sponsor is Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics.

2.1 Cathejell (lignocaine) 2% gel

Cathejell (lignocaine) 2% gel was given provisional consent under section 23 of the Medicines Act 1981 in 2017 and was granted approval in New Zealand in 2018. Cathejell (lignocaine) 2% gel is a clear, water-soluble, clear lubricant gel which comes in 12.5g pre-filled, single-use, accordion shaped plastic syringes in boxes of 5 or 25 units. As this product is classified as pharmacy-only a Datasheet or CMI is not required and as far as we are able to tell there is no approved patient leaflet included in this product. Due to limitations during Covid-19 we have not been able to enter the office to refer to the physical file to confirm this.

Administration instructions for instillation into the urethra:



A separate applicator tip for gynaecology and proctology procedures has been produced to be used in conjunction with Cathejell (lignocaine) 2% gel, however this additional applicator has not been evaluated or approved with the original medicines application and comes in separate packaging.

Comments:

Please note that throughout this paper complaints are discussed refer to the "applicator tip", however, they are in relation to the counter-sunk break off point of the Cathejell applicator, not the additional applicator tip as discussed above.

Samples of the approved Cathejell (lignocaine) 2% gel product and the additional applicator tip were purchased by Medsafe, from a medicine wholesaler, for inspection. This included both the Cathejell (lignocaine) 2% product (i.e. the medicine which has been approved), and an applicator tip, which is treated by the sponsor as a medical device. These can be provided to the MARC if requested. We noted on inspection that the applicator tip seemed to be moulded from a softer material than the break-off tip.

Comments:

The Cathejell product and additional applicator tip was also inspected by one of Medsafe's medical advisors, and it was in his opinion that a break-off tip was not suitable for urethral use.

2.2 Data sheets

Cathejell (lignocaine) 2% gel is a Pharmacy Medicine. The company has not supplied either a Data Sheet or Consumer Medicine Information to Medsafe for publication. As the product is not a prescription medicine this is not a requirement.

2.3 Usage

Cathejell (lignocaine) 2% gel is approved for surface anaesthesia and lubrication for:

- The male and female urethra during cystoscopy, catheterization, exploration by sound and other endourethral operations.
- Nasal and pharyngeal cavities in endoscopic procedures such as gastroscopy and bronchoscopy.
- Proctoscopy and rectoscopy.
- Tracheal intubation.
- Cytoscopy and symptomatic treatment of painful cystitis and urethritis.

2.4 Complaints received by the DHB's

On 21 June 2019 Medsafe received an email from the Clinical Product Advisor for [redacted] expressing their concerns following PHARMAC's announcement to award sole-subsidy Cathejell. At this time there was an alternative, funded product available on the market.

[redacted]

[redacted]

[redacted]

2.5 Section 36 Notice

On 19 November 2019, Medsafe issued the company a notice under section 36 of the Medicines Act 1981 (attached at Annexe 1).

The section 36 notice requested that the company provide safety and efficacy data to support the continued consent for the distribution of Cathejell (lignocaine) 2% gel in New Zealand, consisting of an evaluation of the safety and efficacy issues outlined in the notice and any other appropriate information in support of the safety and efficacy of their product.

The company's response to the section 36 notice is presented in section 3 of this report.

Comments:

The New Zealand sponsor for Cathejell (lignocaine) 2% gel *at the time the section 36 notice was issued was Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics. Shortly after receiving the notification a self-assessable change notification was submitted to Medsafe to change the sponsor to KSJ Pharmatech Limited. Pharm. Fabrik Montavit Ges.m.b.H (Montavit) in Austria are the manufacturer of* Cathejell (lignocaine) 2% gel *and has provided the formal response to the section 36 notice. For the purpose of this report, all three are referred to as 'the company'.*

3 INFORMATION PROVIDED BY THE COMPANY

3.1 Response to the section 36 notice

[redacted]

3.1.1 A summary of the product's safety and efficacy

[redacted]

[redacted]

[redacted]

3.1.2 Complaint investigation process of the safety and efficacy issues outlined in the section 36 notice

[redacted]

[redacted]

[redacted]

3.1.3 Root Cause

[redacted]

3.1.4 Risk Identification

[redacted]

3.1.5 Risk Analysis

[redacted]

3.1.6 Risk Statement

[redacted]

3.1.7 Corrective and preventative actions (CAPA) implemented following the section 36 notice

[redacted]

3.2 CARM data

The complaints regarding Cathejell (lignocaine) 2% gel were mostly centred around the countersunk break off point rather than the active ingredients. Some DHB's and hospitals have incorrectly understood this product to be a medical device and have subsequently submitted a Medical Device Adverse Event Report (detailed in section 2.4).

However, this product is registered as a medicine in NZ, not a medical device.

No CARM reports have been submitted for Cathejell (lignocaine) 2% gel.

4 DISCUSSION AND CONCLUSIONS

Complaints have been received from various DHBs regarding the patient risk and complaints regarding Cathejell (lignocaine) 2% gel. The complaints appear to relate to the design of the product (sharp edges, accordion syringe) which has resulted in injury to patients and the need to use multiple syringes on a single patient.

Cathejell (lignocaine) 2% gel is an approved medicine in New Zealand, but an unapproved applicator has been proposed to be used in conjunction with Cathejell (lignocaine) 2% gel to reduce patient risk/harm.

As Cathejell (lignocaine) 2% gel is classified as a pharmacy-only medicine a Datasheet or CMI has not been published (as it is not a requirement), and there is no patient leaflet provided with the product.

The company have disagreed with the concerns outlined in the section 26 notice, but have proposed that a third party company could provide training to customers/users as a possible corrective action to reduce the risk.

5 ADVICE SOUGHT

The Committee is asked to advise whether:

- The balance of benefit and patient risk for the use of Cathejell (lignocaine) 2% gel (Lignocaine 2% Gel) for use as a surface anaesthetic and lubrication for catheterisation (and other approved uses, see section 2.4).
- Any regulatory action is required to improve the balance of benefits and patient safety risk.

6 ANNEXES

1. Medsafe. 2019. Section 36 notice concerning Cathejell (lignocaine) 2% gel (19 November 2019).

2. Montavit. 2019. Response to section 36 notice concerning Cathejell (lignocaine) 2% gel (18 January 2019).

3. Montavit. 2019. Update Cathejell (lignocaine) 2% gel product training manual.

7 REFERENCES

None.