

# **DRUG SAFETY NOTICE**

#### DRUG NAME/STRENGTH/FORM:

# LIDOCAINE 1% OR 2% WITH ADRENALINE (1:200,000)

#### **PROBLEM**

- There is currently a national shortage of lidocaine (Xylocaine®) 1% and 2% with adrenaline 1:200,000 solution for injection vials.
  - Xylocaine® 1% with adrenaline 1:200,000 is expected to return April 2024
  - Xylocaine® 2% with adrenaline 1:200,000 is expected to return May 2024.
- Due to similar problems in other countries, it is proving difficult to procure unlicensed products.
- SWB has no stock remaining.

## **ADVICE / ALTERNATIVE**

- The only licensed product available is in the form of dental cartridges: Lidocaine 2% with Adrenaline 1:80,000 (2.2ml Cartridges).
- Since there are no other ready-to-use products, preparation using individual components for immediate use is required. Due to this being an unlicensed manipulation, their use is at the discretion of the prescriber.
  - o To make up 1ml of 1% lidocaine with 1:200,000 adrenaline See Appendix 1
  - o To make up 1.1ml of 2% lidocaine with 1:200,000 adrenaline See Appendix 2

### **ACTIONS**

- Exercise caution when prescribing, preparing, and administering the product.
  - The resulting mixture will be unlicensed, and its use will be at the discretion of the prescriber.
  - In line with the SWBH Medicines Policy, a second check by a registered healthcare professional is mandatory for the preparation and administration of a parenteral product. Calculations must be checked independently.
- Do not practice against this memo once the licensed products become available in your area.
- Pharmacy will provide a stock supply of separate lidocaine and adrenaline products (or for them to be added to your ward/clinical area medicines stock list)
- Ensure that you are not administering this unlicensed product against a PGD.



- PGD legislation does not allow for unlicensed medicines to be supplied and/or administered against a PGD. This includes the mixing of 2 or more licensed medicines to form a new (unlicensed) product.
- A medical or non-medical prescriber will need to prescribe individual prescriptions in clinical areas that usually rely on PGDs
- Cascade this memorandum amongst your areas and ensure all staff are aware.
- Refer to local guidance, the BNF, and contact relevant specialist teams for advice on management of individual cases.

## **Key Documents**

- SWBH Medicines Policy
- Unlicensed Medicines Prescribing and Using (Pt Care060) SWBH
- Intravenous (IV) Medicines Preparation, Administration and Monitoring (Pt Care026) (SWBH)

# **Appendix 1:** Making 1% Lidocaine with 1:200,000 Adrenaline.

(1ml of 1% Lidocaine with 1:200,000 Adrenaline contains lidocaine hydrochloride monohydrate Ph. Eur., equivalent to 10mg of lidocaine hydrochloride anhydrous and 5 micrograms of adrenaline (epinephrine) as the acid tartrate).

To make 1ml\* of 1% Lidocaine with 1:200,000 adrenaline, you will require:

- 1 x Lidocaine hydrochloride 2% w/v solution for injection (10ml Mini-Plasco)
- 1 x Dilute Adrenaline (Epinephrine) Injection 1:10,000 (ampoules) (10ml Ampoule)
- 1 x Sodium Chloride 0.9% w/v

#### Step 1

- 1. Using Lidocaine hydrochloride 2% w/v solution for injection, draw up 0.5ml to a 1ml syringe. Total volume thus far is 0.5ml (1ml contains 20mg lidocaine hydrochloride- therefore 0.5ml of 20mg/ml solution gives us 10mg in
- 0.5ml).

  2. Using Dilute Adrenaline (Epinephrine) Injection 1:10,000 (ampoules), draw up 0.1ml

(10 micrograms) of the 100 micrograms solution in a separate 1ml syringe.

- (1 ml contains 100 micrograms of Adrenaline (Epinephrine) as the Acid Tartrate)
- 3. Make up the syringe to 1ml with sodium chloride 0.9%. This syringe now contains 10 micrograms of adrenaline in 1ml.
- 4. Draw 0.5ml (5 micrograms) of this solution and transfer to the syringe containing the lidocaine.

#### Step 2

- 5. On initial mixing please inspect the product for signs of precipitation, crystallisation, and discolouration.
- 6. Protect from light if not used immediately as adrenaline is light sensitive.

- 7. Due to the absence of antimicrobial excipients, the product should be used immediately.
- 8. The final 1ml syringe should now contain 10mg lidocaine and 5mcg adrenaline.

# **Appendix 2:** Making 2%\* Lidocaine with 1:200,000 Adrenaline.

(1ml of Lidocaine 2% with adrenaline (epinephrine) 1:200,000 solution for injection contains lidocaine hydrochloride monohydrate Ph. Eur., equivalent to 20 mg of lidocaine hydrochloride anhydrous and 5 micrograms of adrenaline (epinephrine) as the acid tartrate).

To make 1.1ml\*\* of 2% Lidocaine with 1:200,000 adrenaline, you will require:

- 1 x Lidocaine hydrochloride 2% w/v solution for injection (10ml Mini-Plasco)
- 1 x Dilute Adrenaline (Epinephrine) Injection 1:10,000 (ampoules) (10ml Ampoule)
- 1 x Sodium Chloride 0.9% w/v
- 1. Using Lidocaine hydrochloride 2% w/v solution for injection, draw up 1ml (20mg) of this solution into a 2ml syringe. Total volume thus far is 1ml.
- Using Dilute Adrenaline (Epinephrine) Injection 1:10,000 (ampoules), draw up 0.5ml (50 micrograms) into a 1ml syringe.
  - (1 ml contains 100 micrograms of Adrenaline (Epinephrine) as the Acid Tartrate)
- 3. Make up the syringe to 1ml with sodium chloride 0.9%. This syringe will now contain 50micrograms of adrenaline in 1ml.
- 4. Draw up 0.1ml (5 micrograms) of this solution and add to the 2ml syringe containing 1ml of lidocaine.

#### Step 2

- 1. On initial mixing please inspect the product for signs of precipitation, crystallisation, and discolouration.
- 2. Protect from light if not used immediately as adrenaline is light sensitive.
- 3. Due to the absence of antimicrobial excipients, the product should be used immediately.
- 4. The resulting 1.1ml solution now contains 20mg of lidocaine hydrochloride and 5 micrograms of adrenaline.

<sup>\*</sup>To make up larger volumes, scale up proportions of lidocaine and adrenaline. See appendix 3 for common volumes.

<sup>\*</sup>Due to the availability of lidocaine solution rather than anhydrous powder, the final volume of the resulting solution will be 1.1ml. Please also note the final concentration is slightly less than 2%

<sup>\*\*</sup>To make up larger volumes, scale up proportions of lidocaine and adrenaline. See

Appendix 3



# **Appendix 3:** Volume Calculation

## 1% Lidocaine with 1:200,000 Adrenaline

	Amounts required for total volume	
Total Volume	Lidocaine	Dilute Adrenaline
	hydrochloride 2% w/v	(Epinephrine) Injection
	solution	1:10,000
1ml	10mg	5mcg
10ml	100mg	50mcg
20ml	200mg	100mcg
40ml	400mg	200mcg
50ml	500mg	250mcg

## 2% Lidocaine with 1:200,000 Adrenaline

	Amounts required for total volume	
Total Volume	Lidocaine	Dilute Adrenaline
	hydrochloride 2% w/v	(Epinephrine) Injection
	solution	1:10,000
1.1ml	20mg	5mcg
11ml	200mg	50mcg
22ml	400mg	100mcg
44ml	800mg	200mcg
55ml	1000mg	250mcg

FOR FURTHER INFORMATION CONTACT

PHARMACY DEPARTMENT: CITY x5263; SANDWELL x3783

DATE OF ISSUE: 04/12/2023 REFERENCE NUMBER: 01-1223