AGUETTANT
MÉDICAMENTS
ESSENTIELS

7th September 2020

Dear Healthcare Professional

Laboratoire Aguettant in agreement with the Health Products Regulatory Authority, would like to inform you of the following:

Summary

- Laboratoire Aguettant received marketing approval for a new Suxamethonium product, Murexal 10 mg/ml, solution for injection in pre-filled syringe which will be launched on the Irish market in October 2020
- The dosage strength for Murexal 10mg/ml, solution for injection in pre-filled syringe, is expressed in terms of mg of suxamethonium chloride anhydrous per ml. This is not aligned with formulations which are currently available on the Irish market which have a dosage strength of 50mg/ml and which express the dosage strength in terms of mg of suxamethonium chloride dihydrate per ml, as outlined within the table below:

	New Product	**Existing Products**	
	Murexal 10 mg/ml solution for injection in pre-filled syringe	**Anectine 50mg/ml** solution for injection or infusion	**Suxamethonium Chloride 50mg/ml Solution for Injection (Mercury)**
Presentation	Pre-filled syringe	Ampoule	Ampoule
Composition	Each 10 ml contains 100 mg of Suxamethonium Chloride **anhydrous** (equivalent to 110 mg of Suxamethonium Chloride dihydrate).	Each 2ml contains 100mg Suxamethonium Chloride **dihydrate**	Each 2 ml of solution contains Suxamethonium Chloride 100 mg (50 mg/ml) **dihydrate**

Background on the safety concern

The concentration of Suxamethonium Chloride in solution can be expressed in **anhydrous** form (European Pharmacopoeia) and **dihydrate** form (British Pharmacopoeia). The anhydrous form contains 10% more Suxamethonium Chloride than the dihydrate form.

The therapeutic dose of suxamethonium in several literature publications is reported to range from 0.6 to 1.5 mg/kg. A median of 1 mg/kg is recommended by most guidelines in order to cover the broadest patient populations and clinical situations. Therefore, a 10% difference in dose administered is not anticipated to have an impact on safety or efficacy.

Murexal should be prescribed as recommended by the product SmPC without considering the difference in concentration.

Please read the enclosed Summary of Product Characteristics for full details.

Laboratoire Aguettant
1, rue Alexander Fleming - 69007 LYON - France - Tel. +33 (0) 4 78 61 51 41 - Fax: + 33 (0) 4 78 61 09 35 - **www.aguettant.com**
SAS au capital de 12 697 000 Euros - 447 800 210 RCS Lyon - APE 2120 Z

Call for Reporting

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 national reporting system: HPRA Pharmacovigilance, Website: www.hpra.ie.

Adverse reactions should also be reported to the distributor of this product, namely Aguettant Ltd on +353 (0)1 431 1350

Company contact details

If you have any question or require further information, please contact the distributor of this product, namely Aguettant Ltd by phone on +353 (0)1 431 1350 or via email at info@aguettant.co.uk

Kind regards

PO Anthony OLIVIER
Deputy Global QP

Jérôme JOLY
Global Qualified Person and Quality Director
Laboratoire Aguettant

Annie-Claude BENICHOU
Global QPPV
Laboratoire Aguettant