

## Sodium chloride (SPOT-List)

Sodium chloride, both oral and eye formulations are one of the top 15 items on the PrescQIPP SPOT-List (Specials Prescribing Optimisation Tool). The SPOT-List aims to optimise prescribing of specials by offering alternatives, or by suggesting how to contain prescribing of the particular special. From December 2016 to February 2017 in England and Wales, over £150,000 was spent on sodium chloride specials and the majority of spend was for the oral solution and eye preparations. Sodium chloride can be used for a range of indications; however this bulletin will focus on the use of specials for the oral solution and eye preparations.

### Recommendations

- Consider prescribing Slow Sodium® (containing approximately 10mmol each of Na<sup>+</sup> and Cl<sup>-</sup>) tablets for sodium chloride deficiency first line if a tablet formulation and the dose are suitable for the individual patient.
- When a liquid sodium chloride preparation is required, the licenced Sodium Chloride 292.5mg/5ml (1mmol/ml) Oral Solution sugar free may be preferable if this meets the clinical needs of the patient. It is licensed for the correction of mild to moderate hyponatraemia in infants. It must be prescribed exactly as written in the Drug Tariff to avoid potential specials costs as an item not in part 8 item (NP8) of the Drug Tariff.
- Consider switching patients on unlicensed sodium chloride 1.5g in 5ml, 5mmol/ml and 1mmol/ml oral solutions to a licensed product if clinically suitable for the patient and after discussion with the specialist if necessary. There is also a food supplement available that is called SodiClor 5mmol/ml which may suit the patient's clinical needs.
- Patients should be counselled when switching to alternative preparations to ensure that there is no confusion on the dose.
- Advise patients to purchase Sodium Chloride 0.9% w/v Eye Drops Solution from a pharmacy as part of self care.
- When the decision has been taken to prescribe sodium chloride 0.9% w/v eye drops preservative free, prescribe as "Sodium chloride 0.9% eye drops 0.5ml unit dose preservative free". MINIMS® Saline 0.9% eye drops 0.5ml unit dose is the current cost-effective licensed brand which will be issued against this prescription and is included in Part VIIIA of the Drug Tariff.
- Should sodium chloride 5% eye drops be required, prescribe using the precise wording for the preparations as outlined in the Drug Tariff Part IXA - Appliances, as other unlicensed preparations are more costly, e.g. ODM5 eye drops preservative free (Sodium Chloride 5% eye drops, PF Drops Sodium Chloride 5% eye drops preservative free, Hypersal 5% Eye Drops, or Sodium Chloride 5% Eye Drops (Alissa)).
- Prescribe sodium chloride 5% eye ointment preservative free as worded in the Drug Tariff Part IXA Appliances "Sodium Chloride 5% (Alissa Healthcare) (5g preservative free tube)" as alternative unlicensed products are expensive.
- Do not add oral and eye sodium chloride preparations prescribed as specials to the repeat prescription template, so that the continued need is regularly reviewed.

## Background

From December 2016 to February 2017, in England and Wales, over £150,000 was spent on sodium chloride specials and the majority of spend was for the oral solution and eye preparations. This bulletin focuses on the use of these specials and offers alternative suggestions to optimise prescribing.

Specials are unlicensed medicines, and have not have been assessed by the licensing authority for safety, quality and efficacy. The ideal situation is to prescribe an appropriate UK licensed medication. If a licensed product is not suitable to meet the patient's needs, consider off-label use of a UK licensed medicine. This could be off-label as it is outside of the licensed indications or because the tablet has been crushed and dispersed or the capsule has been opened. Consult product literature to see if this is a licensed option. This may not be a suitable option for all patients; consideration should be given to whether the patient or carer is able to administer medication in this manner and the dose required as drawing off aliquots from a dispersed product is not ideal but may sometimes be necessary. It should be understood that the prescriber's responsibility and potential liability are increased when prescribing off-label. However, this is better than the use of an un-assessed, unlicensed products which holds more risk.

Products listed as 'NP8' items are preparations not included in Drug Tariff Part VIII A/B and are currently responsible for increasing prescribing costs as they are often categorised as unspecified specials. A number of manufacturers, wholesalers and suppliers have recently begun to detail generic products not included in Drug Tariff Part VIII A/B under a heading of 'NP8' or 'NP8 scheme' on their websites with price lists and promotional material. Prices for these products are often significantly higher than those in the Drug Tariff.<sup>1</sup> This is applicable to both oral and eye sodium chloride preparations. Table 1 shows the products currently that appear in the Drug Tariff.

## Introduction

Most sodium chloride deficiency is treated with the licensed preparation of sodium chloride Ph.Eur (Slow Sodium® 600mg tablets [approximately 10 mmol each of Na<sup>+</sup> and Cl<sup>-</sup>]). In July 2015, Sodium Chloride 1 mmol/ml Oral Solution was granted a product license for the correction of mild to moderate hyponatraemia in infants.<sup>2</sup> The only eye formulation that is considered a medicine is sodium chloride Ph. Eur 0.9% w/v (Minims® Saline 0.9% w/v Eye Drops Solution), which is licensed for use as a topical ocular irrigating solution.<sup>3</sup> A significant range of sodium chloride products are considered as appliances in Part IXA of the Drug Tariff.<sup>4</sup>

## Oral sodium chloride preparations

In some cases, adult patients may require sodium chloride for sodium chloride deficiency.

Hyponatraemia is defined as a serum sodium concentration <135mmol/l and is usually associated with a disturbance in antidiuretic hormone (ADH) secretion.<sup>5</sup> This can be through physiological (for example hypovolaemia), pathological (for example heart failure), or iatrogenic (for example thiazide diuretics) mechanisms.<sup>5</sup> In most cases of hyponatraemia, there is an inability to suppress ADH. However, in rare cases, ADH is suppressed but there is either excess water intake (primary polydipsia) or a reduced threshold for the release of ADH which impairs renal excretion of excess water.<sup>5</sup> Hyponatraemia is often found as a result of a routine blood test. Rapid changes in sodium levels or severe hyponatraemia can cause symptoms such as vomiting, drowsiness, headache, seizures, coma and cardio-respiratory arrest due to cerebral oedema and raised intracranial pressure.<sup>5</sup> Chronic mild hyponatraemia can lead to gait instability, falls, and concentration and cognitive deficits.<sup>5</sup>

People with asymptomatic, mild hyponatraemia (serum sodium concentration of 130–135 mmol/L) may be managed in primary care.<sup>5</sup> In all people, ensure a repeat serum sodium measurement has been taken to exclude a rapidly decreasing serum sodium concentration that will require admission to hospital.<sup>5</sup> If the person has an acute illness that may be contributing to the hyponatraemia, treat the underlying problem and recheck the serum sodium concentration after two weeks or sooner based on clinical judgement.<sup>5</sup>

If the person is taking a drug that may be contributing to the hyponatraemia, stop this if appropriate, and recheck the serum sodium concentration after two weeks.<sup>5</sup> If the person is taking a drug that cannot be stopped (for example an antipsychotic drug), contact their appropriate specialist to discuss whether to stop the drug, monitor the serum sodium concentration, or refer to an endocrinologist or nephrologist.<sup>5</sup> If the serum sodium concentration remains low after stopping the drug, look for another underlying cause, or refer the person to an endocrinologist.<sup>5</sup>

The BNF for Children outlines indications where oral sodium chloride may be indicated, these include; chronic renal salt wasting, sodium supplementation in neonates and sodium replacement.<sup>6</sup> Slow Sodium® tablets are licensed for use in children and may be suitable if the child is able to swallow tablets and the tablet strength allows for the correct dosage to be given.<sup>7</sup> Until recently there was no licensed oral solution available, and prescribers were required to either prescribe the licensed dispersible tablets or an unlicensed oral solution.

The highest total spend for sodium chloride oral solution was for the 5mmol/ml solution, accounting for approximately 60% of the total spend on unlicensed oral sodium chloride products during April-June 2016.

For patients that require the oral solution, it would first be necessary to discuss with the specialist if there is an alternative treatment option for the patient's condition. If a special was still required and could not be fulfilled with a licensed preparation, it would be recommended that the secondary care prescriber should consider retaining prescribing responsibility in view of continued monitoring and safety aspects.

Sodium Chloride 1 mmol/ml Oral Solution is made by Martindale Pharma, the marketing authorisation is held by Viridian Pharma Ltd and a license was granted for the correction of mild to moderate hyponatraemia in infants in July 2015.<sup>2</sup> The specific product characteristics state a warning that the product must be diluted in drinks, breast milk or formula feed before administration and that treatment with Sodium Chloride 1mmol/ml Oral Solution should only be initiated under the supervision of specialist paediatric physicians.<sup>2</sup> The dosage should be adjusted if necessary according to clinical need and after plasma sodium monitoring.<sup>2</sup> In some cases it may need to be continued beyond the acute setting. Where possible monitoring and prescribing should be managed by the specialist if the patient has an ongoing need. Where possible patients should only be switched to a licensed product under the supervision of a specialist.

SodiClor 5mmol/ml (equivalent to 1.46g in 5ml) is available as a food supplement and is manufactured by Arjun Products.<sup>8</sup> The recommended doses are; under 1 month, 2mmol/100ml formula milk or 3-4mmol/100ml breast milk; >1 month, usually 1-2mmol/kg daily in divided doses diluted with water. This may be a suitable alternative for some patients.<sup>8</sup>

## Sodium chloride preparations for the eye

Minims Saline 0.9% w/v Eye Drops Solution is the only eye formulation of sodium chloride Ph. Eur 0.9% w/v which has a product license and is for use as a topical ocular irrigating solution.<sup>3</sup> As it is a Pharmacy Medicine, patients requiring this product should be advised to purchase the product over the counter as part of self care.

A significant range of sodium chloride eye products are classified as appliances in Part IXA of the Drug Tariff.<sup>4</sup> The highest total spend for sodium chloride eye preparations was for sodium chloride 5% eye ointment, accounting for approximately 90% of the total spend on sodium chloride eye preparations during December 2016 - February 2017.

Sodium chloride 5% eye drops are used for the short-term treatment of corneal oedema of various aetiology, including bullous keratopathy.<sup>8</sup> Normally one to two drops are instilled in the eye every three to four hours. Sodium chloride eye ointment requires less frequent instillation and is generally reserved for night-time use.<sup>9</sup> In clinical practice, the 5% concentration appears to be effective.<sup>9</sup> There

## B186. Sodium chloride (SPOT-List) 2.0

are several proprietary products available; Hypersal® 5% eye drops (preservatives Methylparaben and Propylparaben) and Sodium Chloride 5% eye drops (Alissa) manufactured by Alissa Healthcare (preservatives PHMB, boric acid, sodium tetraborate), both are listed as part IXA-Appliances in the Drug Tariff.<sup>10</sup>

When a patient is prescribed an unlicensed sodium chloride 5% eye ointment, it may be worth considering switching the patient to the licensed sodium chloride 5% eye drops, as often the ointment is recommended for night time as it has better contact time with the eye, causing the least visual disruption to the patient. As it is expected that corneal oedema will be a short-term problem, sodium chloride 5% eye drops should not be added to the list of repeat prescriptions.

The Royal College of Ophthalmologists. Ophthalmic - Special Order Products, General Principles recommend the following;<sup>9</sup>

- When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products.
- Certain products, e.g. sodium chloride 5%w/v eye drops and sodium chloride 5%w/w eye ointment are now available as prescribable medical devices in certain parts of the UK, these should be prescribed in preference to an unlicensed medicine.
- Where a licensed product is not available, standard Drug Tariff products are preferred e.g. hypromellose 0.3%w/v or 0.5%w/v rather than 0.25%w/v.
- Where a preservative-free (PF) preparation is clinically necessary, licensed Single Dose Units (SDUs) or licensed multi-dose devices e.g. Tear-Lac® should be prescribed if available.
- Excipient intolerances should be included on the prescription (some licensed and unlicensed products including those labelled preservative-free contain potentially sensitising excipients).
- Preservative-free preparations should only be used for a limited period once opened. Justified and validated in-use shelf lives should be provided by the manufacturer.
- Single dose units should be used once only in accordance with the licence.

**Table 1: Drug Tariff costs of licensed products<sup>4</sup>**

Name	Quantity	Cost	Drug tariff	Company
Sodium chloride 292.5mg/5ml (1mmol/ml) oral solution sugar free	100ml	£30.20	Part VIIIA Category C	Viridian Pharma Ltd
Sodium chloride 1.46g/5ml (5mmol/ml) oral solution (SodiClor)	100ml	£19.55	Part VIIIA Category C	Arjun Products
Sodium chloride 600mg modified-release tablets (Slow Sodium) (approx. 10 mmol each of Na <sup>+</sup> and Cl <sup>-</sup> )	100	£6.05	Part VIIIA Category C	H K Pharma Ltd
Sodium chloride 0.9% eye drops 0.5ml unit dose preservative free	20	£7.14	Part VIIIA Category C	Minims saline

## B186. Sodium chloride (SPOT-List) 2.0

Name	Quantity	Cost	Drug tariff	Company
Sodium Chloride 5% Eye Ointment	5g tube (preservative free)	£22.50	Part IXA- Appliances	Alissa Healthcare
Hypersal 5% Eye Drops	10ml	£25.25	Part IXA- Appliances	Ennogen Healthcare Ltd
Sodium Chloride 5% Eye drops	20 x 0.45ml (preservative free single dose unit)	£19.70	Part IXA- Appliances	Essential Pharmaceuticals Ltd
ODM5 eye drops preservative free (Sodium chloride 5% eye drops)	10ml preservative free bottle	£24.00	Part IXA- Appliances	Kestrel Ophthalmics Ltd
PF Drops Sodium Chloride 5% eye drops preservative free	10ml preservative free bottle	£25.20	Part IXA- Appliances	Rayner
Sodium Chloride 5% Eye drops	10ml bottle	£25.25	Part IXA- Appliances	Alissa Healthcare
Xailin Wash	20 x 5ml preservative free single dose unit	£5.71	Part IXA- Appliances	Nicox

As there are now licensed alternatives, there is limited need for using a special for both oral and eye sodium chloride preparations. In addition, where possible review for continued need, as many preparations could be stopped. Most uses are usually for short-term use, and where there is a continued need consider using the licensed products as listed above and consider adding to acute prescriptions rather than repeat template. Ensure that products are written as specified in the Drug Tariff to avoid unintentional additional costs such as NP8 products.

If 100% of patients prescribed an unlicensed special were reviewed and switched to a licenced product, **there would be approximately £218,000 savings annually across England and Wales. This equates to £355 per 100,000 patients.**

**If 50% of patients prescribed a liquid product were switched to slow sodium tablets. This could save approximately £102,000 annually which equates to £165 per 100,000 patients.**

See visual data pack for more detailed information:

[https://pdata.uk/views/B186\\_SodiumchlorideSPOT-List/FrontPage?:embed=y&:showAppBanner=false&:showShareOptions=false&:display\\_count=no&:showVizHome=no](https://pdata.uk/views/B186_SodiumchlorideSPOT-List/FrontPage?:embed=y&:showAppBanner=false&:showShareOptions=false&:display_count=no&:showVizHome=no)

## References

1. NHS Business Services Authority. Hints & Tips Dispensing Contractors Issue 16. [http://www.nhsbsa.nhs.uk/Documents/PrescriptionServices/Dispensing\\_Contractors\\_-\\_Issue\\_16\\_\(final\)\\_07.2014.pdf](http://www.nhsbsa.nhs.uk/Documents/PrescriptionServices/Dispensing_Contractors_-_Issue_16_(final)_07.2014.pdf)
2. Summary Product Characteristics - Sodium Chloride 1 mmol/ml Oral Solution. Martindale Pharma. Last updated on eMC 12 October 2016. Accessed October 2016. Available on-line at: <https://www.medicines.org.uk/emc/medicine/32237>
3. Summary Product Characteristics- Minims® Saline 0.9% w/v Eye Drops Solution Bausch & Lomb UK Limited. Last updated on eMC 10 August 2015. Accessed December 2016. Available on-line at: <http://www.medicines.org.uk/emc/medicine/433>
4. National Health Service Drug Tariff for England and Wales. August 2015 Electronic Drug Tariff. Accessed via <http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx>
5. Clinical Knowledge Summaries: Hyponatraemia Accessed March 2017 via <https://cks.nice.org.uk/hyponatraemia>
6. Joint Formulary Committee. British National Formulary Children (online) London: BMJ Group and Pharmaceutical Press; Accessed October 2016 via <https://www.medicinescomplete.com/mc/bnf/current/>
7. Summary of Product Characteristics- Slow Sodium. HK Pharma Limited. Last Updated on eMC 27 July 2015. Accessed February 2017. Available on-line at: <http://www.medicines.org.uk/emc/medicine/813>
8. Mims online- SodiChlor. Accessed July 2017 via <http://www.mims.co.uk/drugs/nutrition/electrolytes/sodiclor>
9. Clinical Ocular Pharmacology (Fifth Edition), Edited by: Jimmy D. Bartlett, OD, DOS, ScD, and Siret D. Jaanus, PhD, LHD.
10. Royal College of Ophthalmologists. Ophthalmic Special Order Products, General Principles. Accessed December 2016 via [https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2014\\_PROF\\_304\\_Ophthalmic-Special-Order-Products-updated-Nov-14.pdf](https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2014_PROF_304_Ophthalmic-Special-Order-Products-updated-Nov-14.pdf)

## Additional PrescQIPP resources



Data pack

Available here: [https://pdata.uk/views/B186\\_SodiumchlorideSPOT-List/FrontPage?embed=y&:showAppBanner=false&:showShareOptions=false&:display\\_count=no&:showVizHome=no](https://pdata.uk/views/B186_SodiumchlorideSPOT-List/FrontPage?embed=y&:showAppBanner=false&:showShareOptions=false&:display_count=no&:showVizHome=no)

Information compiled by Rakhi Aggarwal, PrescQIPP CIC, July 2017 and reviewed by Katie Taylor, Senior Medicines Evidence Reviewer, September 2017.

Non-subscriber publication January 2017.

Contact [help@prescqipp.info](mailto:help@prescqipp.info) with any queries or comments related to the content of this document.

This document represents the view of PrescQIPP CIC at the time of publication, which was arrived at after careful consideration of the referenced evidence, and in accordance with PrescQIPP's quality assurance framework.

The use and application of this guidance does not override the individual responsibility of health and social care professionals to make decisions appropriate to local need and the circumstances of individual patients (in consultation with the patient and/or guardian or carer). [Terms and conditions](#)