Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Thamicarb 84mg/ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of solution contains 84mg of sodium hydrogen carbonate (equivalent to 1mmol/ml sodium and hydrogen carbonate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Thamicarb is used to treat hyperacidity, dyspepsia and symptomatic relief of heartburn and peptic ulceration.

Thamicarb is also indicated for the treatment of metabolic acidosis in adults with chronic kidney disease.

4.2 Posology and method of administration

Posology

For acid indigestion

Adults and children over 12 years:
Take 12ml (1g) to 60ml (5g) every 4 to 6 hours.

Not recommended for use in children under 12 years of age.

For metabolic acidosis in chronic kidney disease

Adults (including elderly)
Metabolic Acidosis: Dosage is calculated on an individual basis and administered according to the acid-base balance and electrolyte status.

Children
There is no experience using Thamicarb in the management of metabolic acidosis in children.

Method of administration
The required dose should be drawn from the container into the graduated syringe using the syringe adaptor (see section 6.6).

4.3 Contraindications

Contraindicated in patients with metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria.

Not to be taken by children under 12 years old.

4.4 Special warnings and precautions for use

Sodium hydrogen carbonate should be given extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension, eclampsia, aldosteronism, or other conditions associated with sodium retention.

Keep all medicines away from children.

Do not take if you are hypersensitive to sodium hydrogen carbonate.

Consult your doctor or pharmacist if symptoms persist after 7 days.

This medicine can mask the symptoms of stomach cancer or ulcer.

4.5 Interaction with other medicinal products and other forms of interactions

The effects of a number of drugs may be reduced or increased by the alkalinisation of the urine (e.g. aspirin or diflunisal) and changes in gastric pH brought about by sodium hydrogen carbonate.

In particular cases elimination of weak acids and bases may be affected by sodium hydrogen carbonate treatment via an increase of the pH in urine. This might for example apply to sympathomimetics, anticholinergics, tricyclic antidepressants, barbiturates, H2-blockers, captopril, and quinidine.

Sodium-containing preparations should be avoided by patients on lithium because sodium is preferentially absorbed by the kidney resulting in increased lithium excretion and reduced plasma levels.

As a precaution for antacids, in order to minimise the risk of interactions affecting pharmacokinetics of concomitantly administered products, drug administrations should be separated by approximately 2 to 3 hours.

Large amounts of milk or calcium containing products should not be taken whilst taking Thamicarb. Such administration may result in milk-alkali syndrome.

Sodium hydrogen carbonate reduces the absorption of a number of other drugs taken concomitantly. These include ACE inhibitors (captopril, enalapril, and fosinapril), antibacterials and antifungals (azithromycin, cefaclor, cefpodoxime, isoniazid, itraconazole, rifampicin, tetracyclines, ketoconazole and the quinolone group of antibacterials); antivirals (atazanivir, fosamprenavir, tipranavir); antihistamines (fexofenadine); bisphosponates, corticosteroids (deflazacort); digoxin, dipyridamole, antiepileptics (gabapentin and phenytoin), ulcer healing drugs (lansoprazole); levothyroxine, mycophenolate, lipid regulating drugs (rosuvastatin); antipsychotics (sulpiride, phenothiazines), chloroquine, hydrochloroquine, and penicillamine. Antacids should be avoided with nilotinib.

Functional interactions with gluco- and mineralocorticoids, androgens and diuretics associated with increased potassium excretion may occur.

Antacids possibly reduce absorption of bile acids.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies are insufficient with respect to effects on pregnancy, embryonal fetal development, parturition and postnatal development. The potential risk for humans is unknown. Sodium hydrogen carbonate should not be taken during pregnancy unless advised by a doctor to do so.

Breast-feeding
The effects of sodium administration during breast-feeding are not known. Sodium hydrogen carbonate should not be taken if breast-feeding unless advised by a doctor to do so.

Fertility
The potential risks of sodium on fertility are not known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

General adverse effects of sodium hydrogen carbonate are as follows. The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention: very common (≥ 10%), common (≥ 1% and < 10%); uncommon (≥ 0.1% and < 1%); rare (≥ 0.01% and < 0.1%), very rare (< 0.01%), not known (cannot be estimated from the available data).

MedDRA System Organ Class	**Adverse Reaction**
Gastrointestinal disorders:	
Frequency not known	Wind, Nausea, Vomiting, Abdominal Discomfort, Abdominal distension, Flatulence, Unpleasant taste
Metabolism and nutrition disorders:	
Frequency not known	Metabolic alkalosis, Fluid retention, Loss of appetite (continuing)
Psychiatric disorders:	
Frequency not known	Mood or mental changes, Nervousness or restlessness
Vascular disorders:	
Frequency not known	Hypertension, Slow breathing, Breathing difficulties, Fluid on the lungs
Nervous system disorders:	
Frequency not known	Headache (continuing), Dizziness
Skin and subcutaneous tissue disorders:	
Frequency not known	Swelling of feet of lower legs
Renal and urinary disorders:	
Frequency not known	Frequent urge to urinate, Promotion of renal urolithiasis (formation of calcium or magnesium phosphate calculi) upon prolonged use.
General disorders and administration site conditions:	
Frequency not known	Extreme irritability, unusual tiredness or weakness, muscle spasms or cramps

Reporting of suspected adverse reactions
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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Excessive administration of sodium hydrogen carbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, shortness of breath, muscle weakness and irregular heart beat. Muscle hypertonicity, twitching and tetany may develop, especially in hypocalcaemic patients. Excessive doses of sodium salts may lead to sodium overloading and hyperosmolality.

Treatment of metabolic alkalosis and hypernatraemia is by correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium ions may be of particular importance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: A02A H, antacids with sodium hydrogen carbonate.

Sodium hydrogen carbonate is used as an antacid in relief of the symptoms of dyspepsia, heartburn and indigestion caused by excess gastrointestinal acid. Sodium hydrogen carbonate causes neutralisation of gastric acid with the production of carbon dioxide.

Sodium hydrogen carbonate therapy increases plasma hydrogen carbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses clinical manifestations of metabolic acidosis.

5.2 Pharmacokinetic properties

Absorption
Sodium hydrogen carbonate is readily absorbed from the gastro-intestinal tract.

Sodium hydrogen carbonate exists as a sodium ion and hydrogen carbonate ion within Thamicarb 84mg/ml Oral Solution. Once orally administered, the hydrogen carbonate ion readily binds to hydrochloric acid in the stomach to form sodium chloride, carbon dioxide and water.
Hydrogen carbonate ions which do not react with hydrochloric acid within the stomach are readily emptied into the duodenum via the pylorus. Hydrogen carbonate ions are then readily absorbed through the small intestine where they enter general circulation. A linear dose dependent relationship between sodium hydrogen carbonate supplementation and serum hydrogen carbonate levels has been shown in CKD patients with metabolic acidosis.

Distribution
Sodium hydrogen carbonate is present in all body fluids. Sodium hydrogen carbonate causes neutralisation of gastric acid with the production of carbon dioxide.

The hydrogen carbonate ion is freely soluble in the blood stream and readily crosses the blood brain barrier. The site of action of hydrogen carbonate ions with respect to metabolic acidosis is the blood stream.

Biotransformation
The hydrogen carbonate ion is a simple electrolyte and is therefore not hepatically metabolised but rather eliminated from the body via excretion.

Elimination
Any sodium hydrogen carbonate not involved in the gastric acid neutralisation reaction is absorbed. The hydrogen carbonate ion is excreted through various bodily pathways. Firstly, sodium hydrogen carbonate is excreted via the pulmonary system. This involves the hydrogen carbonate ion binding with a free hydrogen ion to form carbonic acid which is then broken down into carbon dioxide and water in the presence of carbonic anhydrase and excreted through the lungs. Hydrogen carbonate ions readily pass through the renal cortex and are eliminated via urine.

5.3 Preclinical safety data

No further relevant information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

12 months.
For 100ml bottle: Discard your medicine 3 days after first opening.
For 500ml bottle: Discard your medicine 7 days after first opening.

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.
Do not use if crystals are observed in the product. For storage conditions after first opening of the medicinal product, see section 6.3.
Keep out of the sight and reach of children.

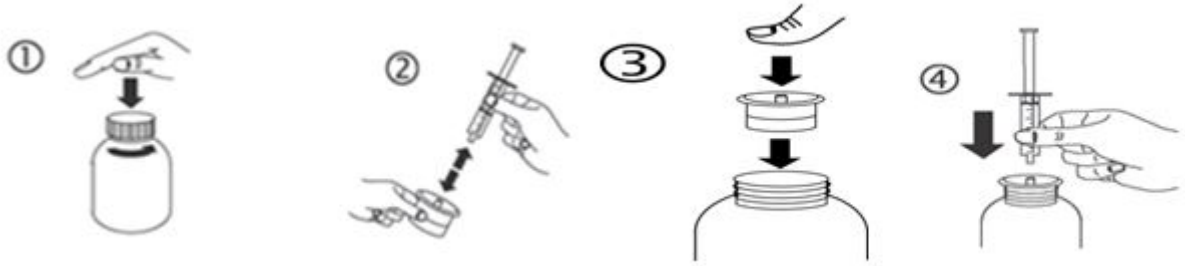
6.5 Nature and contents of container

Bottle: Amber glass
Closure: White tamper-evident child-resistant polypropylene cap with HDPE-EPE wadding.
Pack size: 100ml or 500ml
Dosing Device: 20ml white polypropylene oral syringe with 1ml graduation marks and LDPE syringe adaptor

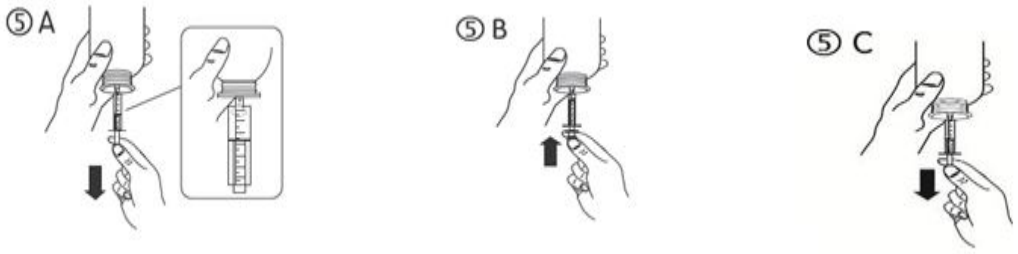
6.6 Special precautions for disposal and other handling

The required dose should be drawn from the container into the graduated syringe provided using the syringe adaptor (see detailed instructions below). The syringe should be held into the mouth of the patient, and the contents of the syringe should then be ejected into the mouth and swallowed.

Instructions for the use of syringe:
a.) Open the bottle: press the cap and turn it anticlockwise (figure 1).
b.) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



c.) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d.) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).

e.) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patients mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).

7 MARKETING AUTHORISATION HOLDER

Syri Pharma Limited t/a Thame Laboratories
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1 WML
1 Windmill Lane
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8 MARKETING AUTHORISATION NUMBER

PA22697/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2014
Date of last renewal: 28th August 2019

10 DATE OF REVISION OF THE TEXT

September 2019