

## **Package leaflet: Information for the user**

### **Thamicarb™ 84mg/ml Oral Solution** (sodium hydrogen carbonate) (1mmol/ml)

#### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Thamicarb 84mg/ml Oral Solution but it will be referred to as Thamicarb throughout this leaflet.

#### **What is in this leaflet:**

1. What Thamicarb is and what it is used for
2. What you need to know before you take Thamicarb
3. How to take Thamicarb
4. Possible side effects
5. How to store Thamicarb
6. Contents of the pack and other information

#### **1. What Thamicarb is and what it is used for**

Thamicarb contains the active substance sodium hydrogen carbonate which belongs to a group of medicines called antacids.

Thamicarb is used to treat hyperacidity, dyspepsia (indigestion) and to provide symptomatic relief from heartburn and peptic ulceration.

Thamicarb is also used to treat metabolic acidosis in patients with chronic kidney disease.

#### **2. What you need to know before you take Thamicarb**

##### **Do not take Thamicarb:**

- if you are allergic to sodium hydrogen carbonate or any of the other ingredients of this medicine (listed in section 6)
- if you have reduced stomach acid
- if you have low levels of potassium in the blood
- if you have low levels of chloride in the blood
- if you have low levels of calcium in the blood
- if you have a liver problem
- if you have toxaemia of pregnancy
- if you have problems with urination
- if you have excess sodium in the blood
- if you are under 12 years old

##### **Warnings and precautions:**

Talk to your doctor or pharmacist before taking Thamicarb:

- if you are on a salt-restricted diet
- if you have heart disease
- if you have high blood pressure or high blood pressure due to pregnancy
- if you suffer from kidney disease or kidney stones
- if you are taking steroids

### **Other medicines and Thamicarb**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicine. This includes medicines obtained without a prescription, also herbal medicines. This is because Thamicarb can affect the way some other medicines work. Also, some other medicines can affect the way Thamicarb works:

- lithium
- aspirin and other salicylates
- ACE inhibitors such as captopril, enalapril and fosinopril
- antibacterials and anti fungals such as azithromycin, cefaclor, cephadoxime, isoniazid, itraconazole, rifampicin, tetracyclines, ketoconazole and the quinoline group of antibacterials
- antivirals such as atazanavir, fosamprenavir and tipranavir
- antihistamines such as fexofenadine
- bisphosphonates
- digoxin
- quinidine (used to treat e.g. heart rhythm disorders)
- dipyridamole
- antiepileptics such as gabapentin and phenytoin
- barbiturates such as phenobarbital
- ulcer healing drugs such as lansoprazole
- levothyroxine
- mycophenolate
- lipid regulating drugs such as rosuvastatin
- antipsychotics such as sulpiride, phenothiazines
- chloroquine
- hydrochloroquine
- penicillamine
- nilotinib
- corticosteroids such as deflazacort
- tricyclic antidepressants
- sympathomimetics (used to treat e.g. asthma, severe allergic reactions, sinusitis or attention deficit hyperactivity disorder)
- anticholinergics (used to treat e.g. asthma, Parkinson, motion sickness, abdominal cramps and urinary tract disorders)

### **Thamicarb with food and drink**

You can take Thamicarb before or after food as directed by your doctor or pharmacist.

**Do not take this medicine with large amounts of milk or milk products or calcium containing products. This may result in milk-alkali syndrome.**

### **Pregnancy and breast-feeding**

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- You should not use this medicine during the first three months of pregnancy unless your doctor feels it is absolutely necessary.

### Driving and using machines

Thamicarb does not affect the ability to drive or operate machinery.

### 3. How to take Thamicarb

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

#### Doses

Your doctor or pharmacist will determine what dose is appropriate for you.

#### 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 failure

##### Adults (including elderly)

In the treatment of metabolic acidosis in patients with chronic renal failure, the dose will be determined by your doctor.

Not recommended for use in children.

Like other antacid preparations, taking Thamicarb may mask the symptoms of other more serious underlying medical conditions like stomach cancer. If there has been no response for more than 7 days then consult with your doctor or pharmacist.

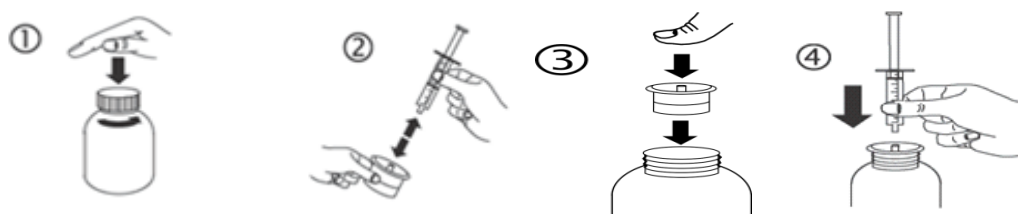
#### Route and method of administration

This medicinal product must be taken orally.

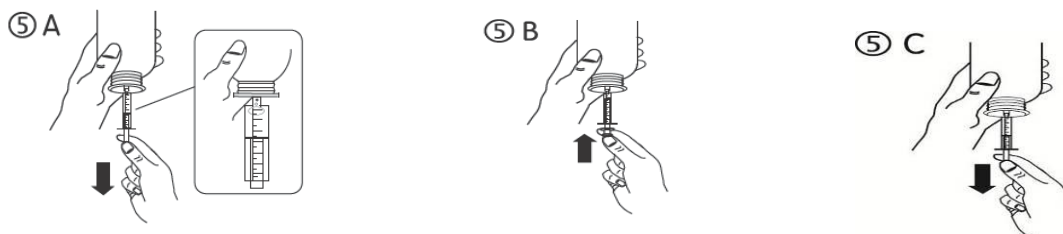
Use the measuring syringe provided in the pack to deliver the required dose.

Instructions for the use of the oral syringe:

- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- 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).



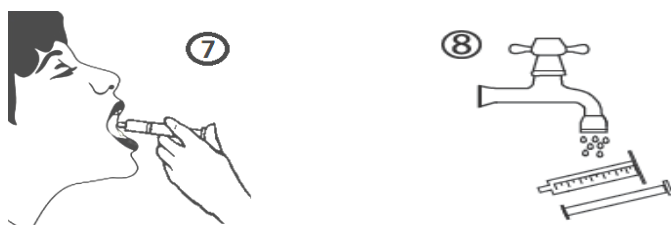
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed 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 patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



#### **If you take more Thamicarb than you should**

- Call your doctor or go to your nearest hospital casualty department straight away. Take the medicine pack with you.
- Overdose may make you feel ill.

#### **If you forget to take Thamicarb**

- If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Contact your doctor immediately if you experience:**

- belching or flatulence
- increased blood pressure
- fluid retention or fluid in the lungs
- frequent urge to urinate

- headache
- loss of appetite
- mood or mental changes
- nausea or vomiting
- nervousness or restlessness
- slow breathing
- swelling of feet or lower legs
- unpleasant taste
- unusual tiredness or weakness
- extreme irritability
- muscle spasms
- increased potassium in the blood
- increased thirst
- stomach cramps
- stomach discomfort
- bloating
- formation of kidney stones with prolonged use
- increased hydrogen carbonate in the blood (metabolic alkalosis).

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Thamicarb**

- Keep this medicine out of the sight and reach of children.
- Do not use after the expiry date which is stated on the carton or bottle after 'Exp'. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not use if crystals are observed in the product.
- For 100ml bottle:  
Discard your medicine 3 days after first opening.
- For 500ml bottle:  
Discard your medicine 7 days after first opening.
- Do not use this medicine if you notice that the solution has become discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Thamicarb contains**

The active substance is sodium hydrogen carbonate.

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

The other ingredient is purified water.

**What Thamicarb looks like and contents of the pack**

Thamicarb is a clear, colourless oral solution supplied in an amber glass bottle, with a tamper-evident, child-resistant white plastic cap with a 20ml oral syringe having 1ml graduation mark and an adaptor for the syringe.

Thamicarb is supplied in a bottle containing 100ml or 500ml oral solution.

Not all pack sizes may be marketed.

**POM****Marketing Authorisation Holder:**

Syri Pharma Limited t/a Thame Laboratories  
Floor 0, 1 WML,  
1 Windmill Lane,  
Dublin 2, D02 F206, Ireland.

**Manufacturer:**

Thame Laboratories  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK.

**OR**

Pharmadox Healthcare Ltd.,  
KW20A Kordin Industrial Park,  
Paola PLA3000, Malta.

**OR**

SyriMed  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK.

**If this leaflet is hard to see or read, please call +44(0) 208 515 3700 for help.**

This leaflet was last revised in 07/2020.

Thamicarb is a registered trademark of Thame Laboratories.