SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Covonia Sore Throat 0.2/0.05%w/v Oromucosal Spray Lemon Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine gluconate 0.2% w/v
Lidocaine hydrochloride monohydrate 0.05% w/v

Excipient(s) with known effect

Each 0.5ml (5 sprays) contains:

Ethanol (alcohol) 30.4 vol %
Propylene Glycol (E1520) 100mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Covonia Sore Throat Spray is indicated for the symptomatic relief of painful, irritated sore throats.

It is a sugar free preparation and can be used by diabetics.

Additional therapy is required in the event of bacterial infection accompanied by fever.

4.2 Posology and method of administration

Adults and children over 12 years

The dose is 3 to 5 sprays (0.3 - 0.5 ml). This can be repeated 6 to 10 times per day.

Children under 12 years
Not recommended.

4.3 Contraindications

Use in children under 12 years.

Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4. Special warnings and precautions for use

Treatment with Covonia Sore Throat Spray should be limited to the relief of existing pain and irritation when strictly necessary. It is not intended for prolonged use, either continuously or repeatedly.

Ingredients with specified warnings

This medicine contains 100mg propylene glycol per 5 sprays (0.5ml).

This medicine contains 120mg of alcohol (ethanol) per 5 sprays (0.5ml). The amount in 5 sprays of this medicine is equivalent to less than 3ml of beer or 2ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Covonia Sore Throat Spray contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be rare. Covonia Sore Throat Spray should not be administered to anyone with a potential history of allergic reaction to chlorhexidine-containing compound (see sections 4.3 and 4.8).

Do not use and consult your doctor if you have difficulty in swallowing. Do not use without consulting your doctor if sore throat is severe or has lasted for more than 2 days or is accompanied by high fever, headache, nausea or vomiting.

Avoid contact with eyes.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is not known to interact with other drugs.

Whilst a number of interactions are theoretically possible with lidocaine these drug interactions are not likely to be clinically relevant to the use of Covonia Sore Throat Spray which is administered topically. Concomitant therapy with drugs that reduce hepatic blood flow (e.g. propranolol, cimetidine) may reduce the clearance of lidocaine. Long term administration with drugs that induce drug-metabolising microsomal enzymes (e.g. phenytoin, barbiturates) may increase dosage requirements of lidocaine. The cardiac depressant effects of lidocaine are additive with those of beta blockers and other anti-

arrhythmics (e.g. mexiletine). Lidocaine is a weak inhibitor of pseudocholinesterase and may prolong the action of suxamethonium. Hypokalaemia produced by acetazolamide, loop diuretics and thiazides may antagonise the effect of lidocaine.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of the safety of lidocaine and chlorhexidine in human pregnancy but they have been in wide use for many years without apparent ill consequence. Covonia Sore Throat Spray should only be used in pregnancy and breast feeding under the direction of a physician.

Lidocaine is excreted in breast milk but in such small quantities that there is generally no risk of the infant being affected at therapeutic dose levels.

4.7 Effects on ability to drive and use machines

No significant effects are known.

4.8. Undesirable effects

Chlorhexidine and lidocaine are usually well tolerated and no unwanted effects have been reported for the product during local short term use.

In extremely rare cases local anaesthetic preparations have been associated with allergic reactions. Hypersensitivity reactions to lidocaine hydrochloride following local injection have presented as localised oedema with slight difficulty in breathing or as a generalised rash.

Chlorhexidine may sometimes produce discoloration of the teeth and tongue. This is not permanent and disappears after treatment when chlorhexidine is discontinued. Occasionally, a dental scale and polish may be necessary to remove the stain completely. Skin sensitivity to chlorhexidine has occasionally been reported, and severe hypersensitivity reactions, including anaphylactic shock, have been reported on rare occasions following the topical use of chlorhexidine. Chlorhexidine may cause transient taste disturbances, a burning sensation of the tongue, and occasional parotid gland swelling.

Nervous System Disorders
Common: Oral paraesthesia/hypoaesthesia

Skin disorders
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

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 the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search MHRA yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The use of oral topical anaesthetic agents may interfere with swallowing and thus enhance the danger of aspiration of food in the respiratory tract. To this end, overdosage with Covonia Sore Throat Spray (use of 10 ml or more) could produce a slight risk of inducing too great a local anaesthetic effect in the glottis region and consequent reduction in control of the swallowing reflex.

Excessively high blood concentrations of lidocaine may produce CNS and/or cardiovascular effects. Early CNS effects may consist of nervousness, dizziness, tinnitus, nystagmus, restlessness, excitation, paraesthesia, blurred vision, nausea, vomiting, and tremors which may progress to medullary depression and tonic and clonic convulsions. Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest.

Although the bioavailability of lidocaine is low it may be sufficient to result in significant toxicity when swallowed. CNS toxicity, seizures and death have been reported following the ingestion of topical preparations. However, in the case of Covonia Sore Throat Spray more than one litre would have to be swallowed to be equivalent to the ingestion of sufficient lidocaine *(0.5* g or more) to cause significant toxicity.

Systemic toxicity from chlorhexidine is rare. The main consequence of ingestion is mucosal irritation.

Treatment of lidocaine overdosage consists of ensuring adequate ventilation and arresting convulsions. Ventilation should be maintained with oxygen by assisted or controlled respiration as required. Convulsions may be treated with thiopentone, diazepam or succinylcholine. As succinylcholine will arrest respiration it should only be used if the clinician has the ability to perform endotracheal intubation and to manage a totally paralysed patient. If ventricular fibrillation or cardiac arrest occurs, effective cardiovascular resuscitation must be instituted. Adrenaline in repeated doses and sodium bicarbonate should be given as rapidly as possible.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D08AC

Lidocaine is a local anaesthetic of the amide type. Like other local anaesthetics, lidocaine impairs the generation and conduction of the nerve impulses by slowing depolarisation. This results from blocking of the large transient increase in permeability of the cell membrane to sodium ions that follows initial depolarisation of the membrane. Lidocaine also reduces the permeability of the resting axon to potassium and to sodium ions.

Chlorhexidine is a bisbiguanide antiseptic and disinfectant which is bactericidal or bacteriostatic against a wide range of Gram-positive and Gram-negative bacteria. It is more effective against Gram-positive than Gram-negative bacteria and some species of Pseudomonas and Proteus have low susceptibility. It is relatively ineffective against mycobacteria. It inhibits some viruses and is active against some fungi.

5.2 Pharmacokinetic properties

Covonia Sore Throat Spray is applied topically for local action in the throat. On swallowing the spray solution or saliva, small amounts may reach the digestive system and some may be absorbed from the oral and pharyngeal mucosa.

Lidocaine is readily absorbed from oral mucous membranes, the gastrointestinal tract and through damaged skin. Absorption through intact skin is poor. Presystemic metabolism is extensive and bioavailability is only about 35% after oral administration. Following absorption, lidocaine is rapidly distributed to all body tissues. It crosses the placenta and blood-brain barrier. Approximately 65% is bound to plasma protein. It has a plasma half-life of 1.6 hours. Lidocaine is largely metabolised in the liver. Any alteration in liver function or hepatic blood flow can have a significant effect on its pharmacokinetics and dosage requirements. Metabolism in the liver is rapid and approximately 90% of a given dose is dealkylated to form monoethylglycinexylidide (MEGX) and glycinexylidide (GX); both of which may contribute to its therapeutic and toxic effects. Further metabolism occurs and metabolites are excreted in the urine with less than 10% of unchanged lidocaine.

Chlorhexidine is poorly absorbed from mucous membranes, intact skin and the gastrointestinal tract. It is only minimally metabolised by the liver and is excreted through bile. Urinary excretion is very low.

5.3 Preclinical safety data

There are no further relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Citric acid monohydrate (E330)
Glycerol (E422)

Sucralose (E955)
Lemon Flavour
Propylene Glycol (E1520)
Ethanol (96%)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
Use within 6 months of first opening

6.4 Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

30ml: Brown, type III glass (E.P.) bottle with a polypropylene/polyethylene metering pump and nozzle.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd

Linthwaite

Huddersfield

HD7 5QH

United Kingdom

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PL 00240/0391

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