SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Covonia Medicated Sore Throat 5mg/1mg Lozenges Menthol Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One compressed lozenge contains 5 mg chlorhexidine dihydrochloride and

1 mg lidocaine hydrochloride monohydrate.

Excipients with known effect: sorbitol (E420)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed lozenges

White to off white, lightly speckled, round compressed lozenges

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic and local treatment at the pharynx. Proposed as disinfectant and local pain-killer of sore throat and disorders of the pharynx and mouth accompanied by irritation. The presence of lidocaine causes a quick alleviation of the symptoms.

In case of a bacterial infection accompanied by fever, a supplementary treatment is required.

Covonia Lozenges Menthol is sugar free and can therefore also be used in diabetic patients.

4.2 Posology and method of administration

Posology

Adults: 6 to 10 tablets per day, to melt slowly in the mouth.

Children from 12 years old: half dose.

This medicine is intended as symptomatic treatment and should not be used on a long-term basis. If there is no improvement within 3 to 4 days of treatment, it is advisable to consult a doctor.

Method of administration

Oromucosal use

4.3 Contraindications

Children younger than 12 years old.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1, and in particular to local anaesthetics such as lidocaine.

4.4 Special warnings and precautions for use

Disinfecting substances do not make sterile; they temporarily reduce the number of micro- organisms at the oral cavity and pharynx.

Restrict the use of this medicine to the necessary alleviation of the existing pain and irritation. It must not be administered on a long term basis, in an uninterrupted or repeated manner.

In view of the presence of levomenthol, caution should be taken when using on young children if there is a history of convulsions.

Avoid the use of this medicine in persons with extreme allergic predisposition.

The use of a too high dose (more than 20 tablets per day) can cause a small risk on too great insensitivity of the glottis area, which can cause a diminished control on the swallowing reflex and food aspiration in the airways can occur.

Covonia Lozenges Menthol contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

The additive effect of concomitantly administered products containing sorbitol (fructose) and dietary intake of sorbitol (fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

4.5 Interaction with other medicinal products and other forms of interaction

Due to possible interferences (opposite action or inactivation) the simultaneous or consecutive use of antiseptics should be avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of lidocaine and chlorhexidine in pregnant women. Animal studies do not indicate reproductive toxicity (see section 5.3).

The use of Covonia Lozenges Menthol may be considered during pregnancy, if necessary.

Breast-feeding

Lidocaine is excreted in breast milk but in small quantities that there is generally no risk of the infant being affected at therapeutic dose levels. There is no data on excretion of chlorhexidine in breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Covonia Lozenges Menthol therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no relevant data on human fertility available. Animal data with lidocaine does not indicate an effect on male fertility in rats. Animal data with chlorhexidine suggests depression of ovarian activity in mice. The relevance of these finding to humans is not known however are limited given the local exposure to the patient with Covonia Lozenges Menthol.

4.7 Effects on ability to drive and use machines

The use of Covonia Lozenges Menthol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Side effects are classified according to organ system with evaluation of the frequency according to the following convention: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1000, < 1/100), rare (≥ 1/10000, < 1/1000), very rare (<1/10000), not known (cannot be estimated from the available data).

Nervous System Disorders
Common: Oral paraesthesia/hypoaesthesia

Immune system disorders (frequency not known)

It should be taken into account that rare allergic reactions of the skin and mucous membrane, which are caused by contact with anaesthetics of the amide-type, such as lidocaine can occur: cases of dermatitis and rashes, which were caused by this product in other circumstances, have been described.

Anaphylactic reactions may occur.

General disorders and administration site conditions (frequency not known)

Taste disorders and a burning feeling on the tongue may occur.

Prolonged and continuous use of chlorhexidine can cause brown-discoloration of the teeth. However, this brown-discoloration is removable.

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 at:

www.mhra.gov.uk/yellowcard or search for "MHRA Yellow Card" in the Google Play or Apple App Store.

4.9 Overdose

Although this medicine contains only a fraction of the toxic dose and although the foreseen use of this composed medicine is limited to local use, the possibility of an overdose by mistake or carelessness should be taken into account, especially in children.

Symptoms of intoxication:

Lidocaine can cause a systematic intoxication (toxic dose for adults from 0.5 g onwards), which affects the central nervous system and the cardiovascular system.

restlessness, yawning, nervousness, tinnitus, nystagmus, muscle tremor, convulsions, depression, dyspnea.

reduced contractility of the heart muscle, peripheral vasodilation, hypotension, bradycardia, disturbed cardiac rhythm, cardiac arrest.

Chlorhexidine is resorbed in very little amounts from the gastrointestinal tract.

Antidote: none.

Treatment:

Systemic intoxication:

Immediately stop the intake of the medicine.

Hospitalization to ensure the respiration, to counteract dehydration and to maintain the blood circulation.

In case of seizures: diazepam

Choking:

Clear the airways, application of the Heimlich-manoeuvre.

If the obstruction persists, hospitalize the patient.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: throat preparations, ATC code: R02AA05

Lidocaine hydrochoride is a local peripheral anesthetic of the amide group, which has a superficial analgesic effect without interfering with motor functions at the point of application.

It acts locally in the form of non-ionised base.

Lidocaine as a local anaesthetic has the same mechanism of action as other medicines from this group in that it prevents generation and conduction of nerve impulses in sensoric, motoric and autonomous nerves. It primarily affects the cell membrane where it blocks the ion channels and thereby reduces the permeability of sodium ions. Due to the progressive propagation of the anaesthetic effect in the nerve, the electric stimulation threshold is increased, impulse conduction is slowed down and the propagation of the action potential is contracted. Finally, the conductivity is interrupted completely. In principle, local anaesthetics block autonomous nerve fibres, small non-myelinated (sensation of pain) and small myelinated (sensation of pain and temperature), more quickly than large myelinated fibres (sensation of touch and pressure).

On a molecular level, lidocaine specifically blocks sodium ion channels in the inactive state, thereby preventing the formation of an action potential. This mechanism prevents the conduction of stimuli when lidocaine is used locally in the vicinity of nerves.

The effect on peripheral nerves is especially important if lidocaine is used as a local anaesthetic. The efficacy-toxicity ratio is favourable. It very rarely causes allergic reactions.

In addition to blocking transmission in peripheral nerves, local anaesthetics affect all the organs in which impulse transmission occurs. Effects on the CNS, autonomous ganglia, neuromuscular junction, and all forms of muscle fibres have

been observed. Lidocaine is also an antiarrhythmic, class 1b.

Chlorhexidine is a cation-active antiseptic agent. It possesses a powerful bactericidal effect against both gram-positive and gram-negative bacteria and an antimycotic effect on dermatophytes and yeasts.

5.2 Pharmacokinetic properties

When taking Covonia Lozenges Menthol the active ingredients are generally released very gradually and they act locally. Small amounts may enter the digestive system if saliva is swallowed.

Chlorhexidine

Absorption

In oral or topical use, absorption of chlorhexidine is insignificant.

In topical use on intact skin, chlorhexidine is absorbed on the outside layers of the skin, providing long-term antimicrobial effect. Pharmacokinetic research has shown that after rinsing the oral cavity, approximately 30% of chlorhexidine is retained, which is slowly released into the saliva.

Distribution

Chlorhexidine binds tightly to saliva proteins.

Biotransformation

Chlorhexidine is not accumulated in the body. Very little of it is metabolized.

Elimination

Following ingestion of a 300mg dose of chlorhexidine gluconate approximately 90% is excreted in faeces via biliary routes and less than 1% is eliminated into urine.

Lidocaine

Absorption

Lidocaine absorption varies, depending on the site and the method of use. It is quickly resorbed from the digestive organs, mucous membranes and through damaged skin.

In healthy adults, no detectable plasma lidocaine levels were noted after use of a 2 % mouth rinse. Children and immune impaired adults do resorb lidocaine from the oral mucosa into the plasma. The levels were approximately 0,2 µg/ml but the toxic plasma concentration is 5 µg/ml.The anaesthetic effect of lidocaine after topical use appears 2 to 5 minutes after application and lasts 30 to 45 minutes. The anaesthetic effect is limited to the surface and does not extend to the submucosal structures.

Distribution

Lidocaine is distributed well in the tissues (kidneys, lungs, liver, heart, adipose tissue).

Lidocaine passes through the blood-brain barrier and placenta and into mother's milk.

Biotransformation

It is metabolised during the first pass through the liver and the bioavailability is about 35 % after oral administration. 90 % is deethylated in the liver to monoethylglycinexylide and glycinexylide. Both primary metabolites are pharmacologically active. Further cleavage of the amide bonds forms the metabolites xylidine and 4-hydroxyxylidine.

Elimination

Lidocaine is eliminated in the form of metabolites through the kidneys. Approximately 10% is eliminated unchanged. The biological half-life of lidocaine is one and a half to two hours in adults. The biological half-life of the primary

metabolites is two to ten hours.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)

Magnesium stearate

Anhydrous Citric Acid

Levomenthol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use Covonia Lozenges Menthol after the expiry date which is stated on the box/the blister after “EXP”.

The first two figures indicate the month, the following two or four figures the year. The expiry date refers to the last day of that month.

6.5 Nature and contents of container

Covonia Lozenges Menthol is available in a box with 12, 24 or 36 compressed lozenges in a perforated unit dose blister.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd

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Huddersfield

HD7 5QH

UK

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PL 00240/0395

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