SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Haemonord 50mg/ml Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains tranexamic acid 50 mg as the active ingredient.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Mouthwash

10ml translucent polypropylene ampoules containing a clear, colourless to slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of dental haemorrhage in patients on continuous oral anticoagulant treatment undergoing dental procedures.

Prevention of dental haemorrhage in patients with haemophilia and other hereditary bleeding disorders.

4.2 Posology and method of administration

Route of administration: Haemonord 50mg/ml Mouthwash should be held in the mouth for 2 minutes and then spat out. Patients should be instructed not to swallow the mouthwash.

The mouthwash should be gently swilled over the affected area and vigorous swilling should be avoided (please see Section 4.4 Special warnings and precautions for use).

Do not eat or drink for one hour after using Haemonord 50mg/ml Mouthwash.

Adults:

One ampoule (10 mL) of the 50 mg/ml solution equivalent to 500 mg tranexamic acid, used four times daily for 2 minutes and expectorated. The recommended duration of dosing is two days to a maximum of five days. The mouthwash should not be swallowed.

Paediatric Population:

For children aged 6-17 years the recommended dose is 5-10 mL of the 50 mg/ml solution used four times a day for 2 minutes and expectorated. The recommended

duration of dosing is two days to a maximum of five days. The mouthwash should not be swallowed. It is advised that children should be supervised to minimise the possibility of swallowing.

In children, for patients haemophilia and other hereditary bleeding disorders, the recommended dose is the same as for adults

Currently available data are described in section 5.1.

Elderly:

No alteration of daily dosage or frequency of dosing, or route of administration are required.

Patients with Renal impairment:

No alteration of daily dosage or frequency of dosing, or route of administration are required. There are no clinical data on tranexamic acid mouthwash use in patients with severe renal impairment requiring dialysis. In patients in whom estimated creatinine clearance is less than 20mL/min, use of Haemonord 50mg/ml Mouthwash should be avoided due to the risk of accumulation (see Section 4.3)

Patients with Hepatic impairment:

No alteration of daily dosage or frequency of dosing, or route of administration are required. There are no clinical data on tranexamic acid mouthwash use in patients with hepatic failure.

4.3 Contraindications

Hypersensitivity to tranexamic acid or any of the excipients listed in section 6.1.
Active thromboembolic disease.
In patients in whom estimated creatinine clearance is less than 20mL/min, use of Haemonord 50mg/ml Mouthwash should be avoided due to the risk of accumulation.

4.4 Special warnings and precautions for use

In order to avoid significant systemic absorption of tranexamic acid it is important to ensure that Haemonord 50mg/ml Mouthwash is held in the mouth for no longer than two minutes and then spat out, and that patients are instructed not to swallow the mouthwash.

Vigorous swilling of the mouthwash should be avoided to prevent displacing blood clots.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies with Haemonord 50mg/ml Mouthwash have been performed. As the plasma levels following use of the mouthwash are minimal

(see Section 5.2 Pharmacokinetic properties), the potential for systemic drug interactions, including counteracting the thrombolytic effect of fibrinolytic preparations, is unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of tranexamic acid in pregnant women. Studies in animals do not indicate teratogenic effects.

Breast-feeding

Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. Therefore, considering negligible systemic absorption of tranexamic mouthwash, an antifibrinolytic effect in the infant is not expected.

Fertility

There are no clinical data on the effects of tranexamic acid on fertility, but no effects should be anticipated following the use of a tranexamic acid mouthwash.

4.7 Effects on ability to drive and use machines

No studies have been performed on the ability to drive and use machines.

Due to low systemic absorption, Haemonord 50mg/ml Mouthwash has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

No systemic reactions have been reported in relation to the use of tranexamic acid mouthwash preparations. There is a potential for hypersensitivity reactions as found with systemically administered products.

Tabulated list of adverse reactions

Adverse reactions reported are presented in table below. Adverse reactions are listed according to MedDRA primary system organ class. Within each system organ class, adverse reactions are ranked by frequency. Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.

System organ class	**Common ≥ 1/100 to < 1/10**	**Uncommon ≥ 1/1,000 to < 1/100**	**Frequency not known (cannot be estimated from the available data)**
Immune system disorders			- Hypersensitivity reactions including anaphylaxis

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

4.9 Overdose

No cases of overdose have been reported.

Symptoms

Based on experience with oral formulations symptoms may include nausea, vomiting, orthostatic symptoms and/or hypotension.

Management

Initiate vomiting, then stomach lavage, and charcoal therapy. Maintain a high fluid intake to promote renal excretion. There is a risk of thrombosis in predisposed individuals. Anticoagulant treatment should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihaemorrhagics, Antifibrinolytics, Amino acids

ATC code: B02AA02

Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The inhibitory effect of tranexamic acid in plasminogen activation by urokinase has been reported to be 6-100 times and by streptokinase 6-40 times greater than that of aminocaproic acid. The antifibrinolytic activity of tranexamic acid is approximately ten times greater than that of aminocaproic acid.

The minimum plasma levels required to achieve fibrinolysis are estimated as 10 -15 μg/mL with lesser or negligible effects found at 5 - 10 μg/mL.

In a study of 24 haemophiliac children undergoing dental extraction, the addition of tranexamic acid mouthwash to standard care resulted in less than 10% of patients developing post-extraction bleeding compared to 25% in control patients.

5.2 Pharmacokinetic properties

Absorption

Twenty healthy volunteers rinsed their mouths with 10 mL of a 5% aqueous tranexamic acid solution for 2 minutes. After mouth rinse, the plasma concentrations did not exceed 2 μg/mL, and plasma concentrations between 1-2 μg/mL, were only noted in 2 of the samples. In contrast the concentrations found in unstimulated whole saliva initially were very high (after 30 minutes mean concentration above 200 μg/mL), remained at a therapeutic level of 7 μg/mL at 120 minutes and decreased to 0.4 μg/mL after 480 minutes.

As a part of a placebo-controlled, double-blind, randomised study of the haemostatic effect of tranexamic acid mouthwash after oral surgery in patients receiving anticoagulants, a subset of the study population (n = 10 for tranexamic acid; 13 for placebo) had analysis of plasma samples which found undetectable levels of tranexamic acid in all but one patient (whose plasma concentration was 2.5 μg/mL).

Peak plasma Tranexamic acid concentration is obtained immediately after intravenous administration (500 mg). Then concentration decreases until the 6th hour. Elimination half-life is about 3 hours.

Distribution

Tranexamic acid administered parenterally is distributed in a two compartment model. Tranexamic acid is delivered in the cell compartment and the cerebrospinal fluid with delay. The distribution volume is about 33% of the body mass.

Tranexamic acid crosses the placenta, and may reach one hundredth of the serum peak concentration in the milk of lactating women.

Elimination

Tranexamic acid is excreted in urine as unchanged compound. 90% of the administered dose is excreted by the kidney in the twelve first hours after administration (glomerular excretion without tubular reabsorption).

Following oral administration, 1.13% and 39% of the administered dose were recovered after 3 and 24 hours respectively.

Plasma concentrations are increased in patients with renal insufficiency.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucralose

Trometamol

Hydrochloric acid

Water for Injections

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years

6.4 Special precautions for storage

Do not use this medicine after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not open the foil pouch until you are ready to use the mouthwash.

6.5 Nature and contents of container

Translucent polypropylene ampoules containing 10 ml of the mouthwash. The ampoules are packed in individual sealed PVC/PE/PVdC clear blister and a two layered paper/aluminium top foil in an outer carboard carton.

Packs of 10 ampoules.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

ParaPharm Development Limited
Building 1410,
Arlington Business Park, Theale,
Reading
RG7 4SA,
United Kingdom

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