SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Product Name> mint lozenges
<Product Name> orange lozenges
<Product Name> honey & lemon lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Lidocaine Hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2, 4-Dichlorobenzyl Alcohol	1.20 mg

Excipients with known effect:

Sucrose	1,495.33 mg
Liquid glucose	1,016.82 mg
Sunset yellow	0,072 mg in orange-flavoured lozenges 0,009 mg in honey-lemon-flavoured lozenges
Cochineal red	0,0125 mg in orange-flavoured lozenges

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge
<Product Name> mint lozenges are green, biconvex, cylindrical, 19 mm diameter, mint-flavoured lozenges.
<Product Name> orange lozenges are orange, biconvex, cylindrical, 19 mm diameter, orange-flavoured lozenges.
<Product Name> honey & lemon lozenges are yellow, biconvex, cylindrical, 19 mm diameter, honey and lemon-flavoured lozenges.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Relief of symptoms of sore throat in adults and adolescents over 12 years of age.

4.2. Posology and method of administration

Posology
Adults and children over 12 years of age:
1 lozenge every 2-3 hours, and when necessary, up to a maximum of 8 lozenges in a 24-hour period (maximum of 4 lozenges for children).

Paediatric population
The medicine is not to be used in children under 12 years of age.

Method of administration
For oromucosal use.
Slowly dissolve the lozenge in the mouth, do not dissolve in the sac of the cheek.

Do not take this medicine before meals or drinking.

The prolonged use of this medicine for more than 5 days is not recommended (see section 4.4).

Elderly:
Adjustment of the dose is not required.

Patients with impaired renal and/or liver function:
There are no data available for use of <Product name>in patients with hepatic or renal impairement.

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

Due to its lidocaine content, it is contraindicated in children under 12 years of age.

4.4. Special warnings and precautions for use

Follow the indicated dosage: when taken in large amounts or repeatedly, this medicine may impact the nervous system as it passes through the bloodstream, possibly causing convulsions or affecting the heart.

The prolonged use of this medicine for more than 5 days is not recommended, as it may alter the natural microbial balance of the throat.

If symptoms persist for longer than 2 days, get worsen or if other symptoms appear, such as high fever, headache, nausea or vomiting, and skin rash, the clinical condition should be evaluated for bacterial infections (angina, tonsillitis).

It should be administered with caution in acutely ill or frail elderly patients, as they are more sensitive to adverse reactions to this medicinal product.

This medicine should not be used in the area of mouth and throat if greater acute wounds exist.

The anesthesia of the throat caused by this medicinal product may lead to pulmonary aspiration (coughing while eating, giving the impression that the person is choking). It is therefore imperative not to take this medicine before meals or drinking.
Asthmatic patients must use this medicinal product under a doctor's care.

<Product name> contains 1.016 g of glucose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

<Product name> contains 1.495 g of sucrose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains terpenes found in levomenthol. Excessive doses of terpenes have been associated with neurological complications such as convulsions in children.

<Product name> may cause numbness of the tongue and may increase the danger of biting trauma. Therefore care should be taken in eating and drinking hot foods. The patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested directly following use of local anesthetic preparations in the mouth or throat area.

Patients allergic to amide-type local anaesthetic drugs should be aware of cross-sensitivity to agents of the amide type such as lidocaine (see section 4.5).

Sunset Yellow and Cochineal red Colourant may cause allergic reactions.

4.5. Interaction with other medicinal products and other forms of interaction

- The simultaneous or successive use of other antiseptics is not advised, due to possible interference (antagonism, deactivation).

Although the dose of lidocaine is low, since it is present in this medicinal product, the following must be considered:

- Beta-adrenergic blocking agents reduce the hepatic blood flow and therefore the speed at which lidocaine is metabolised, resulting in a greater risk of toxicity.

- Cimetidine can inhibit the hepatic metabolism of lidocaine, resulting in a greater risk of toxicity.
- It can cause cross-sensitivity to other local anesthetics of the amide type.

- Class III antiarrhythmics, such as mexiletine and procainamide, due to potential pharmacokinetic or pharmacodynamic interactions.

- The isoenzymes CYP1A2 and CYP3A4 of the cytochrome P450 are involved in the formation of MEGX, the pharmacologically active metabolite of lidocaine, and therefore other medications such as fluvoxamine, erythromycin and itraconazole may increase the plasma concentrations of lidocaine.

4.6. Fertility, pregnancy and lactation

Pregnancy
The safety of <Product name> in pregnancy has not been established.
A large amount of data on the local use of lidocaine during pregnancy indicates no increased risk of congenital malformations. Lidocaine passes the placenta; however, there is very little absorption as a result of the low dose. Animal studies do not indicate reproductive toxicity (see section 5.3).
There are no data on the use of amylmetacresol and 2,4-Dichlorobenzyl Alcohol as pharmacologically active substances during pregnancy. In the absence of documented experience, the use of <Product name> is not recommended during pregnancy.

Breast-feeding
The safety of <Product name> during the period of lactation has not been established. Lidocaine is excreted in small amounts in breast milk. Because of the low dose, no effect of

lidocaine on the infant is anticipated. There are no data on the excretion of amylmetacresol and 2,4-Dichlorobenzyl Alcohol in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from <Product name> therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no data on the effect of use of lidocaine, amylmetacresol and 2,4-Dichlorobenzyl Alcohol on fertility.

4.7. Effects on ability to drive and use machines

This medicinal product has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

During the period of use, the following adverse reactions have been reported for the combination of active substances in this medicinal product:

Immune system disorders
Rare (≥1/10,000 to ≤1/1,000): hypersensitivity reactions (burning, itching), angioedema, stinging of the throat and unpleasant taste.

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 national reporting system.

<The national reporting system per country will be addressed at national phase>

4.9. Overdose

No problems related to overdose are expected. In the case of systemic absorption, the transitory stimulation of the CNS may occur, followed by a depression of the CNS (drowsiness, unconsciousness) and depression of the cardiovascular system (hypotension, slow or irregular heartbeat).

The prolonged use of this medicine (more than 5 days) is not recommended, as it may alter the natural microbial balance of the throat.

Paediatric population
The use in children under 6 years of age in large doses and over long periods of time may cause convulsions.

Symptoms
Given the low level of the active ingredients, overdose is unlikely.
In case of abnormal use (much higher dosage, lesions of the mucous membranes), overdose may occur. This is manifested initially by excessive anesthesia of the upper respiratory and digestive tract. Systemic reactions due to the absorption of lidocaine can occur. The most serious effects of lidocaine include intoxication in the central nervous system (insomnia, restlessness, excitement and respiratory depression) and the cardiovascular system; also methaemoglobinaemie may occur.

Treatment

In the event of an overdose, induction of vomiting, and / or gastric lavage (within one hour) in case of a potentially serious intoxication, may be considered. Additional measures are only used on supportive and symptomatic basis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Throat Preparations, Antiseptics, various.
ATC code: R02AA20.

2, 4-Dichlorobenzyl alcohol and amylmetacresol have antiseptic properties.

Lidocaine is a local anesthetic of the amide type.

5.2. Pharmacokinetic properties

Lidocaine has a half-life of 1 to 2 hours (around 100 minutes), which is dependent on the dose. The half-life of the metabolite glycinexylidide (GX) is longer, and therefore accumulation may occur, especially in case the excretion is renal.
There are no relevant data on the pharmacokinetics of either 2,4-dichlorobenzyl alcohol or amyl metacresol with the exception of a bioavailability study reported in the summary of product characteristics of Benagol (Benagol, 2008) which determines the rapid release of both antiseptics in the saliva, reaching maximum levels in 3-4 minutes after sucking the lozenge.
The amount of 2.4-alcohol dichlorobenzyl and amylmetacresol found in the saliva after 120 minutes is approximately 50% of the amount administered.
In patients with myocardial infarction (with or without heart failure), the half-life of lidocaine and monoethylglycinexylidide (MEGX) is extended; the half-life of (GX) may also be lengthened in patients with heart failure secondary to myocardial infarction. A longer half-life has also been reported for lidocaine in patients with congestive heart failure or liver disease and may last longer following continuous IV infusion lasting more than 24 hours. The elimination of MEGX may also be decreased in patients with congestive heart failure.
Lidocaine is readily absorbed through the mucous membranes. The plasma elimination half-life is approximately 2 hours. Once absorbed, it undergoes significant first-pass metabolism in the liver, and is rapidly de-ethylated to the active metabolite monoethylglycinexylidide, which is then hydrolysed to various metabolites, including glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

5.3. Preclinical safety data

Non-clinical data on 2, 4-dichlorobenzyl alcohol and amylmetacresol revealed no special hazard for humans. These data come from conventional studies of single and repeated dose toxicity, genotoxicity and toxicity to reproduction. Studies on safety pharmacology and carcinogenicity have not been performed.

Genotoxicity studies with lidocaine were negative. The carcinogenicity of lidocaine has not been studied. The lidocaine metabolite 2,6-xylidine has genotoxic potential in vitro. In a carcinogenicity study of rats exposed to 2,6-xylidine in utero, postnatally and throughout their lifetime, tumors in the nasal cavity, subcutaneous tumours and liver tumours were observed. The clinical relevance of tumour findings in relation to short-term/intermittent use of lidocaine is unknown.

In animal studies on reproduction toxicity, there was no evidence of teratogenic effects or evidence of adverse events in the physical development of the offspring following prenatal treatment with lidocaine. However, fetal exposure to high doses of lidocaine affected uterine blood flow and caused fetal convulsions.

Otherwise, non-clinical data on lidocaine do not add any relevant information to the existing clinical experience.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Mint lozenges
Mint oil, partly dementholised,
Star anise oil,
Levomenthol,
Indigo carmine (E-132),
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose.

Orange lozenges
Levomenthol,
Sodium saccharin (E-954),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Cochineal red (E-124),
Citric acid monohydrate (E-330),
Orange flavour.

Honey & lemon lozenges
Mint oil, partly dementholised,
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Lemon essence,
Honey flavour.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

~~27~~ 30 months.

6.4. Special precautions for storage

Do not store above 30ºC.

6.5. Nature and contents of container

PVC-PVDC/Aluminium blisters

24 lozenges
12 lozenges

6.6. Special precautions for disposal and other handling

Any unused medicinal product and all material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

Package leaflet: Information for the user

<Product Name> mint lozenges
<Product Name> orange lozenges
<Product Name> honey & lemon lozenges
Lidocaine Hydrochloride/ Amylmetacresol/ 2, 4-Dichlorobenzyl Alcohol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What <Product name> is and what it is used for

<Product name> contains amylmetacresol and 2, 4 dichlorobenzyl alcohol – both antiseptics, and lidocaine hydrochloride – a local anaesthetic for the throat.
Indicated for the local relief of symptoms of sore throat in adults and adolescents over 12 years of age.
You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

2. What you need to know before you take <Product name>

Do not take <Product name>:
- if you are allergic to lidocaine hydrochloride or other amide-type local anaesthetic drugs, amylmetacresol, 2, 4 dichlorobenzyl alcohol or any of the other ingredients of this medicine (listed in section 6).
- Children under 12 years old should not take this medicine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking <Product name>.
You should inform your doctor if:
- You suffer from asthma.
- Your symptoms do not improve after two days or if you have a fever, headaches, nausea, vomiting or skin rash.

This product may be harmful for the teeth.
• The anesthetics contained in this medicine may cause aspiration (coughing during meals or a choking sensation) while eating. Do not take food directly following the use of this medicine.

This medicine may cause numbness of the tongue and may increase the danger of biting trauma. Therefore care should be taken in eating and drinking hot foods.
• Prolonged use of this medicine (more than 5 days) is not recommended, as it may alter the natural microbial balance of the throat.
• Follow the indicated dosage: if taken in large quantities or over time this medicine may affect the heart or nervous system, and may cause convulsions.
• Elderly persons or persons in a weakened condition are more sensitive to possible adverse reactions and should consult their doctor before taking this medicine.
• This medicine should not be used in the area of mouth and throat if greater acute wounds exist.

<Product name> contains 1.016 g of glucose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

<Product name> contains 1.495 g of sucrose per lozenge, which should be considered when treating patients with glucose-galactose malabsorption and patients with diabetes mellitus.

<Product name> contains terpenes found in levomenthol. Excessive doses of terpenes have been associated with neurological complications such as convulsions in children.

Sunset Yellow and Cochineal red Colourant may cause allergic reactions.

Children and adolescents
This medicine is not to be used in children under 12 years of age.
Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as it may be necessary to adjust their doses:

- Beta blockers (used to treat heart failure or arterial disease) or medicines containing cimetidine (used to treat stomach ulcers).
- Other local anaesthetics (amides).
- Medicines used to treat heart disorders, such as mexiletine or procainamide.
- Medicines such as fluvoxamine (used to treat depression).
- Antibiotics, such as erythromycin or itraconazole.

Although no interactions should occur, do not take other mouth or throat antiseptics while using <Product name>**.**

<Product name> with food, drink and alcohol
Do not take this medicine before meals or before drinking.

Pregnancy and breast-feeding
Pregnancy:
The use of this medicine is not advised during pregnancy.

Breast-feeding:
The use of this medicine is not advised during period of lactation.

Driving and using machines

Observe your response to this medicine. Taken at the recommended dose, this medicine should not affect your reactions or cause drowsiness. However, if you observe either of these effects, avoid driving or operating heavy machinery.

3. How to take <Product name>

Follow the instructions contained in this leaflet. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses are the following:

- Adults and adolescents over 12 years: dissolve one lozenge slowly in the mouth every 2 to 3 hours, up to a maximum of 8 lozenges over 24 hours (maximum of 4 lozenges for children). Do not dissolve in the sac of the cheek.

Use in children and adolescents
The medicine is not to be used in children under 12 years of age.

If you take more <Product name> than you should
Events that may occur in the event of misuse or overdose: excessive anesthesia of the upper digestive and respiratory tract, insomnia, restlessness, excitement, respiratory depression. Shortness of breath, headache, fatigue, exercise intolerance, dizziness and loss of consciousness may also occur due to a disorder called Methemoglobinemia. Seek medical help immediately, or call the Toxicology Information Service specifying the medicine and the amount taken.

It is not recommended to use this medicine over more than 5 days, as it may alter the natural microbial balance of the throat.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
During the period of use, the following adverse reactions have been reported for the combination of active substances in this medicinal product:

You should stop taking <Product name> and see your doctor immediately if you experience symptoms of angioedema, such as
• swollen face, tongue or pharynx
• difficulty to swallow
• hives and difficulties to breath

Immune system disorders
Rare (may affect up to 1 in 1,000 people): hypersensitivity reactions (burning, itching), angioedema, stinging of the throat and unpleasant taste.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

<The national reporting system per country will be addressed at national phase>

5. How to store <Product name>

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

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 30ºC.

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 <Product name> contains
The active substances are:

Lidocaine hydrochloride	2.00 mg
Amylmetacresol	0.60 mg
2,4-dichlorobenzyl alcohol	1.20 mg

The other ingredients are:

Mint lozenges
Mint oil, partly dementholised,
Star anise oil,
Levomenthol,
Indigo carmine (E-132),
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose.

Orange lozenges
Levomenthol,
Sodium saccharin (E-954),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Cochineal red (E-124),
Citric acid monohydrate (E-330),
Orange flavour.

Honey & lemon lozenges
Mint oil, partly dementholised,

Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Lemon essence,
Honey flavour.

What <Product name> looks like and contents of the pack
<Product Name> mint lozenges are green, biconvex, cylindrical, 19 mm diameter, mint-flavoured lozenges.
<Product Name> orange lozenges are orange, biconvex, cylindrical, 19 mm diameter, orange-flavoured lozenges.
<Product Name> honey & lemon lozenges are yellow, biconvex, cylindrical, 19 mm diameter, honey and lemon-flavoured lozenges.

PVC-PVDC/Aluminium blisters.

24 lozenges.
12 lozenges

Marketing authorisation holder and Manufacturer
<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:
<[To be completed nationally]>

This leaflet was last revised in {MM/YYYY}
<[To be completed nationally]>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box

1. NAME OF THE MEDICINAL PRODUCT

<Product Name> mint lozenges
<Product Name> orange lozenges
<Product Name> honey & lemon lozenges

Lidocaine Hydrochloride/ Amylmetacresol/ 2, 4-Dichlorobenzyl Alcohol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each <Product Name> mint lozenges contain 2.00mg Lidocaine Hydrochloride/ 0.60mg Amylmetacresol/ 1.20mg 2, 4-Dichlorobenzyl Alcohol
Each <Product Name> orange lozenges contain 2.00mg Lidocaine Hydrochloride/ 0.60mg Amylmetacresol/ 1.20mg 2, 4-Dichlorobenzyl Alcohol
Each <Product Name> honey & lemon lozenges contain 2.00mg Lidocaine Hydrochloride/ 0.60mg Amylmetacresol/ 1.20mg 2, 4-Dichlorobenzyl Alcohol

3. LIST OF EXCIPIENTS

Mint lozenges
Mint oil, partly dementholised,
Star anise oil,
Levomenthol,
Indigo carmine (E-132),
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose.

Orange lozenges
Levomenthol,
Sodium saccharin (E-954),
Sucrose,
Liquid glucose,
Sunset yellow (E-110),
Cochineal red (E-124),
Citric acid monohydrate (E-330),
Orange flavour.

Honey & lemon lozenges
Mint oil, partly dementholised,
Quinoline yellow (E-104),
Sodium saccharin (E-954),
Tartaric acid (E-334),
Sucrose,
Liquid glucose,

Sunset yellow (E-110),
Lemon essence,
Honey flavour.

4. PHARMACEUTICAL FORM AND CONTENTS

Lozenge

24 lozenges
12 lozenges

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oromucosal use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

For the local relief of symptoms of sore throat in adults and adolescents over 12 years of age.
Dosage: 1 lozenge every 2-3 hours.
See package leaflet for further information.

16. INFORMATION IN BRAILLE

<Product Name> mint
<Product Name> orange
<Product Name> honey & lemon

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE MEDICINAL PRODUCT

<Product Name> mint lozenges
<Product Name> orange lozenges
<Product Name> honey & lemon lozenges

Lidocaine Hydrochloride/ Amylmetacresol/ 2, 4-Dichlorobenzyl Alcohol

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. OTHER