SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Anbesol Teething Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine hydrochloride	1.0%w/w
Chlorocresol	0.1%w/w
Cetylpyridinium chloride	0.02%w/w

Excipients with known effect:
Each 1ml of the product contains 100 micrograms of Ponceau 4R (E124) and 66.605%w/w of ethanol 96%

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal gel

A soft pink clear gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the temporary relief of pain caused by recurrent mouth ulcers and denture irritation.
For relief of pain and discomfort associated with teething in children from 5 months of age, where non-pharmacological treatments have failed to provide sufficient relief.

4.2 Posology and method of administration

Route of administration: oromucosal

Adults and the elderly: Apply a small amount to the affected area with a clean fingertip. Two applications immediately will normally be sufficient to obtain pain relief. It should not be used more frequently than every 3 hours.

Babies teething and children: Apply a pea-sized amount (0.2 grams) of Anbesol teething gel with a clean finger to the affected area.
The dose may be repeated if necessary after 3 hours, up to a maximum of 6 doses in 24 hours.
Treatment should be stopped once symptoms have resolved.
Not to be used for more than 7 days.
Parents or carers should seek medical attention if the child's condition deteriorates during treatment.
In case of vomiting, spitting or accidental ingestion, the dose should not be repeated immediately. The dose may be repeated if necessary after 3 hours.

4.3 Contraindications

Hypersensitivity to the active substances, anaesthetics of the amide-type or to any of the excipients listed in section 6.1.

Lidocaine is considered to be unsafe in patients with porphyria because it has been shown to be porphyrinogenic in animals.

4.4 Special warnings and precautions for use

Do not use more than one product containing lidocaine at the same time.

Excessive dosage, or short intervals between doses, may result in high plasma levels and serious adverse effects (see Section 4.9). Anbesol should be used with caution in patients with wounds or traumatised mucosa in the region of the proposed application. A damaged mucosa will permit increased systemic absorption resulting in systemic effects, such as convulsions, particularly if excessive quantities are used.

This medicinal product contains chlorocresol and the azo dye Ponceau 4R (E124) which may cause allergic reactions in sensitive individuals.

A dose of 0.2g of this medicine administered to a child 5 months of age weighing 5kg would result in exposure to 25.6 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 4.3 mg/100ml.
For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml.
Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

4.5 Interaction with other medicinal products and other forms of interaction

Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. antiarrhythmic drugs such as mexiletine, since the toxic effects are additive.

In patients taking erythromycin the toxicity of oral lidocaine may be markedly increased.

In patients taking itraconazole, the toxicity of oral lidocaine may be markedly increased.

Antiarrhythmic drugs class III (e.g. amiodarone) may incur additive cardiac effects in combination with lidocaine.

Drugs that reduce the clearance of lidocaine (e.g. cimetidine or beta-blockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long time period. Such interactions should therefore be of no clinical importance following short-term treatment with topical lidocaine (e.g. Anbesol) at the recommended dose.

Chlorocresol has long been recognised to be incompatible with a range of compounds including calcium chloride, codeine phosphate, diamorphine hydrochloride, papaveretum, quinine hydrochloride, methylcellulose and non-ionic surfactants such as cetomacrogol 1000 and polysorbate 80.

4.6 Fertility, pregnancy and lactation

Pregnancy:
The safety of this medicinal product for use in human pregnancy has not been established. The product is, therefore, not recommended during pregnancy.

Lactation:
Lidocaine enters the mother's milk, but in such small quantities that there is generally no risk of the child being affected at therapeutic dose levels.

Fertility:
No data on human fertility is available.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.
Assessment of undesirable effects is based on the following frequency groupings:
Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

System Organ Class	Undesirable Effect	Frequency
Immune system disorders	Allergic reactions	Not known

Gastrointestinal disorders	Non-specific ulceration	Not known
Skin and subcutaneous tissue disorders	Dermatitis	Not known

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

Lidocaine:
Systemic features:
CNS Symptoms: Increasing restlessness, visual disturbances, agitation, tinnitus, confusion, hallucinations, drowsiness, weakness, shivering, paraesthesia, and muscle twitching lead to convulsions, which are the major feature of toxicity. Coma and apnoea may develop.

Cardiac Symptoms: Possibly transient hypertension and tachycardia followed by arrhythmias (including sinus bradycardia, AV nodal or ventricular arrhythmias, asystole). The incidence of torsade de pointes is less than with other groups of antiarrhythmics. Hypotension may result from depressed myocardial contractility and peripheral vasodilation.

GI Symptoms: Nausea and vomiting.

Allergic reactions occur rarely and may include urticaria, angioedema, contact dermatitis and pruritis. Acute respiratory distress syndrome (ARDS) has been reported in severe allergic reactions.

Rarely methaemoglobinaemia may occur with excessive exposure to some local anaesthetics. This is much more commonly seen with benzocaine and prilocaine (due to its metabolite o-toluidine) than with lidocaine.

Serious toxicity is usually due to inadvertent intravenous overdosage. It is much less likely after oral administration because of extensive first pass metabolism but has been reported after ingestion of large amounts. Lidocaine is readily absorbed across mucous membranes and through damaged skin.

Systemic toxicity and death have been reported in children and adults following ingestion or aspiration of topical solutions or viscous preparations. The effect may also be due to absorption of high concentrations across the buccal mucosa causing systemic toxicity (see Section 4.4).

Potential toxic doses range from 800mg of gargled lidocaine solution (death), 1200mg ingestion (agitation and confusion) and 6g ingestion (death). Toxicity may also arise from rectal or urethral instillation.

Anaphylaxis or an anaphylactoid reaction has been reported following administration of 1% lidocaine solution for topical anaesthesia prior to fiberoptic bronchoscopy.

Signs of serious toxicity may occur at plasma concentrations greater than 5-8 microgram/mL (5-8mg/L).

Following ingestion bioavailability of lidocaine is 30-35% and peak levels occur within 40 minutes. The elimination half-life is about 1-2 hours. Metabolites of lidocaine have longer half-lives than lidocaine itself as well as antiarrhythmic activity.

All patients who have taken a deliberate overdose should be referred for assessment. Children and adults who have ingested 6mg/kg or more lidocaine, or those who are symptomatic, should be referred for medical assessment.

Children and adults who have accidentally ingested less than 6mg/kg lidocaine and who have no new symptoms since the time of ingestion do not need to be referred for medical assessment. Patients should be advised to seek medical attention if symptoms develop.

Chlorocresol:

Systemic features:

Nausea, vomiting, diarrhoea, hypotension, tachycardia, cardiac arrhythmias, metabolic acidosis, pallor, sweating and shock. CNS stimulation is followed by drowsiness, respiratory depression, cyanosis, convulsions, coma, bronchospasm and rapid onset pulmonary oedema and death. Methaemoglobinaemia is recognised. Phenol may also cause renal and hepatic injury.

Chronic exposure is rare but has been associated with nausea, vomiting, diarrhoea, anorexia, weight loss, hypersalivation, headache, fainting, mental disturbances, weakness, muscle aches and pain, mouth sores, renal and hepatic injury.

Exposure by any route can cause irritation, burns and systemic effects.

Ingestion causes irritation of mucous membranes, and of the GI tract. Significant ingestion is said to cause white/brown skin and mucosal burns which may be painless as phenol destroys the nerve endings. Laryngeal oedema can occur, and oesophageal stricture may be a late complication.

Skin contact – even dilute solutions (1%) can cause irritation, dermatitis and burns to the skin following prolonged contact. Often presents as relatively painless white or brown necrotic lesions; the brown colouration may remain after healing.

Management:

1. Wash area with soap and water.

2. Maintain a clear airway and ensure adequate ventilation. Give oxygen if clinically indicated.
3. Observe for at least 4 hours after exposure. Perform 12 lead ECG. Monitor pulse, blood pressure and cardiac rhythm continuously for 4 hours if the ECG is abnormal or the patient is symptomatic. Measure urea and electrolytes, arterial blood gases, liver and renal function in symptomatic cases and monitor in a critical care facility.
4. If cardiotoxicity is unresponsive to the above consider the use of a lipid emulsion. It is thought lipid may reduce free concentrations of active drug and therefore improve myocardial function, although other mechanisms are also postulated.
5. Correct acid base and metabolic disturbances as required.
6. Institute drug treatment of seizures as per local protocol.

Paediatric populations:
Lidocaine:

In children up to 6mg/kg lidocaine (with chlorhexidine in mouth paint) produced only minor symptoms. A 5 month old child had a seizure after ingestion of 100mg (14mg/kg). Severe toxicity in children is unlikely at doses less than 15mg/kg.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics for topical use

ATC code: D04AB

Lidocaine hydrochloride: Lidocaine is a local anaesthetic of the amide type which acts by reversible inhibition of nerve impulse generation and transmission.
Chlorocresol: Chlorocresol has a disinfectant action.
Cetylpyridinium chloride: Cetylpyridinium chloride has a disinfectant action.

5.2 Pharmacokinetic properties

Lidocaine Hydrochloride
Absorption and fate: Lidocaine is readily absorbed from mucous membranes and through damaged skin. Lidocaine undergoes first-pass metabolism in the liver and about 90% is dealkylated to form monoethylglycinexylidide and glycinexylidide. Further metabolism occurs and the metabolites are excreted in the urine with less than 10% as unchanged lidocaine.
Chlorocresol
Absorption: There is no significant absorption of chlorocresol through the skin or mucous membranes.

Cetylpyridinium chloride:
Absorption: There is no significant absorption of cetylpyridinium chloride through the skin or mucous membrane.

5.3 Preclinical safety data

The active ingredients in Anbesol Teething Gel have a well established safety record.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol 96%
Glycerol
Clove Oil
Sodium Saccharin
Hydroxypropyl Cellulose
Ponceau 4R (E124)
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months unopened.

6.4 Special precautions for storage

Do not store above 25^{o}C

6.5 Nature and contents of container

Membrane sealed lacquered aluminium tubes fitted with plastic caps containing 10g gel.

6.6 Special precautions for disposal

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
Avonbridge House
Bath Road
Chippenham
Wiltshire
SN15 2BB
UK

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