ULTRACARE® TOPICAL ANAESTHETIC GEL
Benzocaine 17.9% w/w

Read all of this leaflet carefully because it contains important information for you.

Ultracare Topical Anaesthetic Gel will be applied at your dental surgery as part of your dental treatment. It is available without a prescription.

- Keep this leaflet. You may need to read it again
- Ask your dentist if you need more information or advice
- You must contact your dentist if your symptoms worsen or do not improve
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist, doctor or pharmacist

In this leaflet:

1. What Ultracare Topical Anaesthetic Gel is and what it is used for
2. Before Ultracare Topical Anaesthetic Gel is applied
3. How Ultracare Topical Anaesthetic Gel will be applied
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1. What Ultracare Topical Anaesthetic Gel is and what it is used for

The name of your medicine is Ultracare Topical Anaesthetic Gel. It is used to:
- deaden the pain of minor dental procedures when no injection of anaesthetic is required
- reduce the pain caused by injection of dental anaesthetic into the gums

2. Before Ultracare Topical Anaesthetic Gel is applied

Do not undergo treatment with Ultracare Topical Anaesthetic Gel if:
- You have had an allergic (hypersensitive) reaction such as rash, itching or wheezing to benzocaine or any of the other ingredients of Ultracare Topical Anaesthetic Gel (see section 6 for other ingredients)
- You have methaemoglobinaemia (a rare blood disorder that reduces the ability of blood to carry oxygen). Symptoms are extreme tiredness, difficulty in breathing and/or skin becomes slightly blue in colour

If you are not sure if the above applies to you, talk to your dentist or healthcare professional before treatment begins.

Take special care with Ultracare Topical Anaesthetic Gel

Check with your dentist before undergoing treatment with Ultracare Topical Anaesthetic Gel:
- If you have phenylketonuria, a rare condition preventing your body breaking down the chemical phenylalanine in your blood
- If you have or have had an allergic reaction to any other local anaesthetic
- If you have or have had an allergic reaction to a sunscreen product

If you are not sure if the above applies to you, talk to your dentist or healthcare professional before treatment begins.

Taking other medicines

Please tell your dentist or healthcare professional:
- If you are taking or have recently taken any other medicines, including medicines obtained without prescription and herbal medicines
- If you are taking or have recently taken sulphonamide antibiotics such as co-trimoxazole for an infection

Pregnancy and breast-feeding

Ultracare Topical Anaesthetic Gel should not be used if you are pregnant, think you may be pregnant or are breast-feeding. It should only be used if it is considered essential by your dentist.

Driving and using machines

Ultracare Topical Anaesthetic Gel has no known effect on the ability to drive or operate machinery. However if you feel very tired do not drive or operate any machinery.

Important information about some of the ingredients
- The colouring agent Allura Red (E129) may cause allergic type reactions
- Aspartame contains a source of phenylalanine. This may be harmful if you have phenylketonuria

3. How Ultracare Topical Anaesthetic Gel will be applied

Your dentist or healthcare professional will apply Ultracare Topical Anaesthetic Gel to those areas of your mouth and gums where local anaesthesia is needed.

Applying this medicine
- Depending on the size of area to be treated, your dentist or healthcare professional will apply 0.2-0.5 ml of the gel to the area with an applicator. The gel is rubbed into the lining of the mouth or the gums
- The gel should start to work within 10 to 30 seconds and cause a tingling followed by numbness where it was applied. The numbness will usually last for only 5 to 10 minutes and will wear off shortly after your dental treatment has finished

If you receive more Ultracare Topical Anaesthetic Gel than you should

The medicine will only be administered in the dental surgery under the direction of a dentist or healthcare professional, and therefore taking too much is extremely unlikely. If you feel you have received more gel than you should, talk to a doctor, your dentist or go to a hospital straight away.

4. Possible side effects

Like all medicines, Ultracare Topical Anaesthetic Gel can cause side effects, although not everybody gets them.

Contact your dentist or doctor immediately if any of the following occur:

- Allergic reactions such as burning or stinging sensation on application, shortness of breath, swelling of the face, lips, tongue, eyes or throat, rash
- Feel very tired, have difficulty in breathing and/or your skin becomes slightly blue in colour. These are symptoms of a serious condition called methaemoglobinaemia

Reporting of side effects

If you get any side effects, talk to your dentist, doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

5. How to store Ultracare Topical Anaesthetic Gel

Your dentist or healthcare professional knows how to store this medicine properly (see section 6).

6. Further information

What Ultracare Topical Anaesthetic Gel contains

- Ultracare Topical Anaesthetic Gel contains 17.9% w/w of benzocaine as the active ingredient. This is equivalent to 6g of benzocaine per 30ml pack
- Other ingredients include macrogols, glycerol, ethanol, aspartame, sodium saccharin, titanium dioxide (E171), Allura Red (E129) and flavouring

What Ultracare Topical Anaesthetic Gel looks like and contents of the pack

- Ultracare Topical Anaesthetic Gel is a pink, bubble-gum flavoured dental gel for topical use on gums and in the mouth
- Ultracare Topical Anaesthetic Gel is available in a 30ml bottle

Marketing Authorisation Holder: Optident Ltd, International Development Centre, Valley Drive, Ilkley, West Yorkshire, LS29 8AL, United Kingdom.

Manufacturer: Laleham Health and Beauty Limited, Sycamore Park, Mill Lane Alton, Hampshire, GU34 2PR, United Kingdom.

MA Number: PL 12139/0003   Leaflet last revised: May 2015

The following information is intended for the Dentist or Healthcare Professional

How to prepare and administer Ultracare Topical Anaesthetic Gel

Aseptic techniques **must be** used when administering this medicine.

Method of Administration

1. Using a suitable unidose syringe, extract the required dose (normally 0.2 - 0.5 ml depending on the area to be anaesthetised) from the bottle of Ultracare Topical Anaesthetic Gel.

2. Express the gel from the unidose syringe onto a clean cotton bud applicator.

3. Ensure the full dose is dispensed.

4. Vacuum excess saliva from mouth.

5. Apply the gel to the area to be anaesthetised using the cotton bud applicator. Discard the cotton bud applicator after single use.

Take the following measures to help prevent cross-contamination of the bottle:

- Use a new unidose syringe per administration per patient
- Dispose of the unidose syringe following use
- Do not place the cotton bud applicator directly into the gel
- Replace the bottle cap immediately after each use
- Dispose of the unidose syringe in clinical waste if it is touched by used gloves

Storage

Do not store above 25°C.

Keep out of the sight and reach of children.

Do not use Ultracare Topical Anaesthetic Gel after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Once the bottle has been opened use within 14 days.

Do not use this Product if you notice any visible change in the appearance of the gel.

Do not dispose of medicines via wastewater. Take care to follow appropriate procedures for the management of healthcare waste. These measures will help to protect the environment.   V13/2015