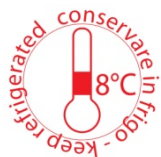




X-PLOSIVE
SMILE SYSTEM



INSTRUCTION FOR USE



CE0425

1. DESCRIPTION

The X-PLOSIVE SMILE 38% whitening gel is used to whiten teeth with dyschromias. The gel is applied directly onto the teeth. The product belongs to class IIa of the Medical Devices 93/42/CEE directive.

For professional use only.

2. COMPOSITION

A) Hydrogen Peroxide 38%. (White)

3. SET PACKAGING AND METHODS OF APPLICATION:

"X-PLOSIVE SMILE 38%": 2 syringes of 2,50 ml whitening gel 38%; 4 mixing cannulas;

Apply for maximum 15 minutes.

N.B. Mixing cannulas are disposable.

These products can be used also with "Curing Lamps". (Please read carefully the Instruction Manual of the Manufacturers.) or "Laser".

In this case we recommend using specific Laser for Bleaching only or Laser of which the Manufacturer arranged – in according with the rules related with Odontoiatric Laser- a specific step by step procedure to use during bleaching. In the Instruction Manual must be written the parameters of use of the laser during bleaching:

- ***diode laser/max wavelength 800 through 1064 Nanometres***
- ***the power (Watt) of the laser to be applied to a tooth (Max 4 Watt) or to more teeth (max 10 Watt)***
- ***The distance to be applied from the laser to the bleaching gel***
- ***Exposure time (Max 45 sec.)***

If you do not know these parameters do not use X-PLOSIVE SMILE 38% with Laser.

4. INDICATIONS

Single parts or several parts affected by dyschromias or devitalisation can be whitened at the same time. The dyschromias may be caused by: medicines, fluorosis, food related stains, alterations due to ageing.

It is advisable to complete the whitening gel treatment at least two weeks before new aesthetic restorations are positioned. Existing restorations, which are not affected by the whitening gel, may not match the lighter colouring of the teeth after treatment and may need to be replaced.

5. CONTRAINDICATIONS

Do not use the product on: patients during pregnancy or when breastfeeding children, heavy smokers or drinkers, patients allergic to any of the product components, teeth with the neck exposed, primary and secondary untreated caries, crowns and bridges with marginal cracks.

6. SIDE EFFECTS

There may be temporary sensitivity of the oral mucosa or teeth; these symptoms usually disappear when the treatment is finished or interrupted.

7. WARNING

X-PLOSIVE SMILE 38% contains hydrogen peroxide, which is an irritant. Use 2 times a year only. Avoid contact of the gel with skin, mucosae and eyes. In case of contact, rinse the affected parts of the body immediately with abundant water; seek medical advice if eyes are affected. Consult your doctor if the irritation persists. In the event of swallowing significant quantities of

the gel, drink plenty of water and seek medical advice. Avoid prolonged exposure of the product to temperatures of over 22°C. Avoid contact of the product with alkaline substances, as they are compatible. Caution: the product catches fire at approximately 204°C.

Close syringes after use. Do not use the Product on patients allergic to any of the product components. Before using the Product final user must check the integrity of product packaging. Dispose of according to local and government regulations.

Do not use other than those foreseen by the field of application for the Product.

8. APPLICATION

In the surgery the dentist carries out an analysis of the patient's case history, determining the suitability for treatment and prescribing the duration and relative checks.

Instructions for the dentist: direct method, to be performed exclusively in the surgery.

- Check that the teeth to be treated are perfectly clean.
- Protect the gums with a rubber dam or specific products. **(Es: X-PLOSIVE SMILE DAM).**
- Apply the product directly onto the surface of the teeth using the mixing cannula.
- Remove the product after about 10/20 min. with gauze and rinse with abundant water.
- Remove the rubber dam or product used to protect the gums.
- If required, make a topical application of fluorine or specific desensitizing agents.
- The procedure can be repeated until the required colour is achieved.
- Reduce the time of contact in patients with extreme tooth sensitivity.
- Check the state of the teeth and gums for the whole duration of the treatment.

9. STORAGE

The temperature of storage is between 5 ° C and 10 ° C. The product should be absolutely protected from exposure to heat or direct sunlight.

For a better and longer preservation of the product, you must keep in a refrigerator at a temperature of 8°C.

Once opened, should be closed with its cap and, if properly stored in a refrigerator at a temperature of 8 ° C, can be used until the expiry date. In the summer it is recommended to keep the product out of the refrigerator for no longer strictly necessary to its use. The expiry date refers to the product stored correctly.

The product must strictly not be used after the expiry date indicated on the package.

Follow proper precautions in accordance with local regulations when disposing of all materials.

10. NOTES

BY DENTAL srl does not accept any responsibility for the wrong conservation of this product.

Keep out of children's reach. To be used exclusively for oral cavities, as described in this explanatory sheet. The product may only be used in keeping with the specific instructions for use. BY DENTAL does not accept any responsibility for damage resulting from failure to comply with the instructions for use or for uses other than those foreseen by the field of application for the product. The user is responsible for experimenting with the material for uses not explicitly described in the instructions for use.



1. DESCRIPTION

X-PLOSIVE SMILE DAM is a light curing dam utilized for gingival protection during a whitening treatment. It can be easily placed due to its fluid consistency and it is an ideal seal of the interproximal spaces. **X-PLOSIVE SMILE DAM** is filled in syringes and can be placed on the gingiva in absence of bubbles. After the treatment it is easily to remove from the dental area.

The product belongs to class I of the Medical Devices 93/42/CEE directive.

For Professional use only

N.B.: FlowTips are disposable

2. COMPOSITION

Resin based on dimetacrilic aliphatic and aromatic monomers

3. SET PACKAGING

X-PLOSIVE SMILE DAM: 1 syringe of 3cc, 3 Flow Tips, 1 instruction for use

4. INDICATIONS

Gingival protection used during whitening treatment.

5. CONTRAINDICATIONS

X-PLOSIVE SMILE DAM cannot be used on patients allergic to any of the product components and other than those foreseen by the field of application explained in this user manual.

6. WARNING

It's recommended use of protection gloves, goggles and glasses. Avoid contact with eyes: if happens, rinse with abundant water and get medical attention. Avoid skin contact. Don't swallow the product.

Before using the product final user must check the packaging integrity. Dispose of in according to local regulation.

7. APPLICATION

- Remove the protective cap with an anti-clockwise turn and insert the flow tip. Put the cap back on after usage.
- Make sure that the teeth you wish to treat perfectly clean.
- Apply **X-PLOSIVE SMILE DAM** in order to create a 4-6 mm layer on the gingiva.
- Extend the **X-PLOSIVE SMILE DAM** application on dry enamel for about 0.5 mm.
- Extend the BLEACH MASK Light Curing to the adjacent teeth. Seal all interproximal spaces. Make sure that the gingiva is protected.
- The polymerisation time when using a curing light is approximately 20/40 seconds.
- Apply the whitening gel according to its instructions for use.
- Rinse and wash thoroughly after the procedure.

8. STORAGE

Store the product at a temperature of between 5° and 10°C inclusive, away from exposure to sources of heat or direct sunlight. Syringe must be closed with its cap after usage and, if correctly stored, can be used since expiry date. The expiry date refers to the product stored correctly. The product must strictly not be used after the expiry date indicated on the package.

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with the instructions for use or for uses other than those foreseen by the field of application for the product. The user is responsible for experimenting with the material for uses not explicitly described in the instructions for use.



1. DESCRIPTION AND COMPOSITION

X-PLOSIVE SMILE DESENS is a professional dentine desensitizing treatment based on Potassium Nitrate 20% in aqueous solution. **X-PLOSIVE SMILE DESENS** is filled in vials and can be set directly on teeth with the suitable brush (Ultrabrush 2.0) contained inside package. The product belongs to class I of the Medical Devices 93/42/CEE directive.

For Professional use only

Composition: Potassium Nitrate 20%

2. KIT

X-PLOSIVE SMILE DESENS : 5 Vials 0.5 ml , 5 Ultrabrush 2.0, 1 Instruction for use.

3. INDICATIONS

Dentine desensitizing agent.

4. CONTROINDICAZIONI

X-PLOSIVE SMILE DESENS cannot be used other than those foreseen by the field of application explained in this instruction for use.

5. WARNING

Don't swallow the product. Avoid contact with eyes: if happened, rinse with abundant water and get medical attention. Avoid skin contact. Keep away from child's range. Do not use the Product on patients allergic to any of the product components. Before using the product final user must check the packaging integrity. Dispose of in according to local regulation. Do not use other than those foreseen by the field of application for the Product.

6. APPLICATION

a) X-PLOSIVE SMILE DESENS

- Dip Ultrabrush 2.0 in the vial
- Apply very careful on interested dental area or on prepared dentine for at list 30 sec.
- Be sure that the area going to be treated is well imbibed
- The product can be placed on wet surface
- Do not affect soft tissue
- Dry gently for 30 sec.
- If you don't use air jet, let it dry for 2 minutes.

7. STORAGE

Store the product at room temperature, away from exposure to sources of heat or direct sunlight. The expiry date refers to the product stored correctly. The product must strictly not be used after the expiry date indicated on the package.

8. NOTE

BY DENTAL srl does not accept any responsibility for the wrong conservation of this product.

Keep out of children's reach. To be used exclusively for oral cavities, as described in this explanatory sheet. The product may only be used in keeping with the specific instructions for use. BY DENTAL does not accept any responsibility for damage resulting from failure to comply with the instructions for use or for uses other than those foreseen by the field of application for the product. The user is responsible for experimenting with the material for uses not explicitly described in the instructions for use.

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Manufacturer: BY DENTAL srl – Pistoia – Italy- www.bydental.com



expire date



lot number;



read the instruction for use



min 5 °C
max 10 °C
storage temperature