

1 Intended Purpose

A dental bleaching gel is a product used to brighten teeth that are devitalized or discoloured by diseases, injuries, medicines or iatrogenically.

2 Description of product and user

2.1 Product description

JW NEXT Power Bleaching is used by the dentist to whiten one or more teeth, including endodontically treated teeth. **JW NEXT Power Bleaching** contains bleaching gel and activator in a self-mixing 4:1 double syringe (cartridge). The hydrogen peroxide content in the pre-mixed gel is 35%.

2.2 Patient target group

For use in all patients who need teeth whitening of devital or by disease, injury, iatrogenic or drug-related discolored teeth.

2.3 Users

JW NEXT Power Bleaching is used by the dentist in the practice.

3 Composition

Water, hydrogen peroxide, potassium nitrate, sodium fluoride, sodium hydroxide, glycol derivatives, thickening agent, colouring

4 Indications

- Brightening of discoloured, devitalised teeth
- Brightening of discoloured teeth caused by disease, by injury or iatrogenically, as alternative to a crown or veneer.
- Treatment of tooth discolourations caused by prescription drugs (e.g. tetracycline)

5 Contraindications

- Exposed dentine
- Defective filling margins
- Hypersensitive patients
- Allergy to or intolerance of ingredients
- Pregnancy and lactation (due to insufficient data)

Some patients may experience slight sensitisation in their teeth during or shortly after treatment, but this normally subsides after a short time.

Treatment should be discontinued immediately if undue pain is being experienced.

6 Warnings

Danger. Contains hydrogen peroxide solution. Causes serious eye damage.

7 Precautionary instructions

Wear eye protection / face protection. IN CASE OF CONTACT WITH THE EYES: Rinse gently with water for a few minutes. If possible, remove any existing contact lenses. Continue to rinse. Call the POISON INFORMATION CENTER/doctor immediately.

8 Interactions with other agents

The dentist should consider known interactions and cross-reactions of the medical product with other materials already in the patient's mouth before using the product.

9 Application

9.1 Preparatory work

Determine the tooth color by comparing it with the Vita® Shade Guide. To evaluate the colors, please re-sort the Vita® Shade Guide as follows:

Values sorted by hue:

A1 A2 A3 A3.5 A4 B1 B2 B3 B4 C1 C2 C3 C4 D2 D3 D4

Sorted according to brightness value:

B1 A1 B2 D2 A2 C1 C2 D3 A3 D4 B3 A3.5 B4 C3 A4 C4

B2 to B1 = values are increased twofold, A3 to A2 = values are increased fourfold

Use air flow or a cleansing paste to clean the patient's teeth. Use a cheek/lip retractor or similar instrument and protect the gingiva. Do not anaesthetise the patient.

9.2 Application on discolored teeth

First remove both the fixing clamp and the sealing cap, facing away from the patient and from yourself. Replace the sealing cap with a mixing tip. Now squeeze the gel from the syringe until a homogeneously colored mass with gel-like consistency emerges from the tip. Discard the initial inhomogeneous mass.

Storage for long periods at high temperatures may occasionally cause bubbles to form in the gel. This can also lead to inhomogeneous and more liquid mixtures, especially in the last quarter of the dual syringe. If this occurs, do not use the affected parts of the material.

The gel should be applied in a thickness of about 1-2 mm to the labial surfaces of the teeth to be bleached. The point of the mixing tip is designed to spread the gel evenly.

A standard plasma arc light or laser may be used to enhance the effect. **In this case, both the patient and professional should wear safety goggles.** Please follow the manufacturer's instructions. Do not overheat!

After a treatment time of about 10 minutes, aspirate the gel and wipe off the residue. If the bleaching effect is insufficient, the procedure can be repeated twice until the desired effect has been achieved.

Before each treatment, ensure that the gingiva protection is still sufficient. Then determine the tooth color again.

After the final bleaching procedure, aspirate the gel, wipe it off and then rinse thoroughly with water. Now dry the tooth surface and polish with polishing paste. Subsequently, follow-up treatment with After Bleaching Care or a fluoride solution/fluoride gel is recommended. This is also suitable for treating pain if sensitisation occurs.

If there is still enough material for another bleaching treatment, remove the mixing tip and replace the blue cap. Store the material in a refrigerator. Use a new mixing tip for the next treatment. The patient should refrain from eating, drinking or smoking for 1 hour after treatment. Highly staining substances such as red wine or coffee, and foods containing acid should also be avoided in the days immediately following the treatment.

Note: Any composite fillings and restorative materials made of ceramic or metal are not bleached. Fillings should therefore be replaced 2 weeks after treatment.

9.3 Application on devitalised or endodontically treated teeth

The gel is also applied through an access opening on the lingual side of the tooth. First, check the height of the alveolar ridge. Next, remove all of the filling material from the pulp chamber.

Now apply one layer of glass ionomer filling with a thickness of 1-2 mm to the bottom of the pulp chamber at the same level as the alveolar ridge or coronally. Apply the gingiva protection to both the labial and the lingual sides of the tooth.

Now apply the bleaching gel to the labial surface as described under "Application" above, and additionally apply the gel through the access opening, letting the gel act for 10 min. Then carefully aspirate the gel and lightly rinse with water. If the bleaching effect is insufficient, this procedure can also be repeated twice until the desired effect has been achieved.

After the procedure is complete, aspirate the gel and rinse thoroughly with water. Carefully remove the gingiva protection. Then close the access opening with a temporary filling material which does not contain eugenol. Wait two weeks before fixing the final filling.

10 Troubleshooting / FAQList

Problem	Remedy
Insufficient bleaching effect	Repeat the bleaching procedure (several times if necessary)
Patient is experiencing pain	The gel has come into contact with exposed dentine or a loose filling (please cover before treatment). The patient is particularly sensitive (depending on the individual tooth structure)
There are white spots on the enamel after the bleaching procedure	Local demineralisation or dehydration. Reversible. Disappears after fluoridation.
Gingiva is coloured white after bleaching (procedure can be reversed)	The gingiva is not adequately protected, or the protection is loose
The gel from the cartridge has an inhomogeneous colour (colourless / red)	The gel has air bubbles in it as a result of being too stored at too high a temperature or for too long
Reduced composite-enamel adhesion after bleaching procedure	Peroxide residue. Leave for 1 - 2 weeks before restoration.

11 Information on storage and handling

Storage temperature 3°C – 9°C.

12 Shelf life

The maximum shelf life is printed on the label of each syringe. Do not use after the expiration date.

13 Warnings on side effects

With proper preparation and use of this medical product, adverse effects are extremely rare. Immune reactions (such as allergies) or local discomfort, however, cannot be ruled out completely. All serious incidents which occur in connection with the use of this product are to be reported to the manufacturer indicated below and the competent authority in each case

14 Instructions for disposal

Leftover quantities and packaging materials are to be disposed of according to the local and/or statutory regulations.

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