

Concerns on the use of tooth whitening or bleaching products containing hydrogen peroxide

Issue

The Irish Medicines Board is warning Irish consumers of its concerns relating to the use of tooth whitening or bleaching products which contain excessive amounts of hydrogen peroxide.

What is the concern?

Tooth whiteners contain or release hydrogen peroxide, an ingredient which has whitening properties. Hydrogen peroxide whitens teeth by passing into the teeth and reacting with the molecules that cause stains or discoloration. A common adverse effect of tooth bleaching is dental hypersensitivity. Hydrogen peroxide is taken up into dental pulp causing minor inflammation leading to pain.

Particular care in using tooth whitening products should be taken by persons with gum disease (gingivitis and other periodontal diseases) or defective restorations (fillings, crowns etc).

Due to the increasing risks of acute and long-term effects, tooth whitening products containing more than 0.1% hydrogen peroxide are not permitted for use without dental supervision.

Why must a dentist supervise the tooth whitening procedure?

A clinical examination by a dentist prior to using such tooth whitening products will ensure the absence of any pre-existing oral tissue injury which may exacerbate the possible toxic effects of hydrogen peroxide. It is also recommended that users consult with their dentist prior to using the lower strength tooth whitening kits to ensure the absence of pre-existing oral tissue injury.

How do I know if a tooth whitening product is safe to use?

Tooth whitening products made available directly to consumers, for example through retail or pharmacy sale, should not contain more than 0.1% hydrogen peroxide (present or released). Consumers should check the level of hydrogen peroxide with the retailer or pharmacist prior to purchasing.

Consumers undergoing professional tooth whitening procedures, which involve the use of products containing more than 0.1% hydrogen peroxide should ensure that this is carried out by a dentist or under their direct supervision.

Tooth whitening procedures carried out by beauty salons or clinics should not involve the use of products containing greater than 0.1% hydrogen peroxide. Due diligence and care should be taken by salons when sourcing such products from suppliers, to ensure that those sourced are compliant with this limit. Product safety updates, listing products that pose a risk to consumers, are available on the European Commission's website at: www.ec.europa.eu/consumers.

Tooth whitening products are classified as cosmetic products and not as medical devices. Products bearing a CE mark and marketed as medical devices are incorrectly classified as such and should be brought to the attention of the IMB.

All cosmetic products must be labelled with an ingredient list. In the case of tooth whitening products, hydrogen peroxide should be declared on the label. In some instances, ingredients that

release hydrogen peroxide are used in the product formulation. These include the following ingredients: carbamide peroxide, calcium peroxide, magnesium peroxide, zinc peroxide, sodium carbonate peroxide, sodium perborate, strontium peroxide and urea peroxide. Tooth whitening products containing any of these ingredients are subject to the same compositional restrictions as those containing hydrogen peroxide.

What checks must I carry out if I purchase a cosmetic product over the internet?

When buying a cosmetic product over the internet for your own use, you should be mindful of the following:

- Check the ingredients carefully for the presence of hydrogen peroxide or a substance that releases hydrogen peroxide (see list above)
- Check the country of origin of the product; product manufactured outside of Europe must have a dedicated European responsible person for that product and the location of the responsible person must be declared on the label
- Check if there are warnings and precautions listed on the label including the level of hydrogen peroxide present
- If the concentration of hydrogen peroxide is listed as greater than 0.1% do not use the product
- Follow all directions of use carefully

Please refer to our website for further information on the legal obligations of the Responsible Person www.imb.ie.

What should I do if I experience an undesirable effect after using the product?

If you experience an undesirable effect following use of a tooth whitening product, stop using the product immediately and contact your dental practitioner. You should report all complaints and/or effects directly to the Responsible Person whose details should be on the product packaging. We recommend that all serious undesirable effects are also reported directly to the Irish Medicines Board (cosmetics@imb.ie) and to the Responsible Person.