

ANNEX

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE
OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

The Member States shall ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Member States shall agree the details educational materials with the MAH according to national regulations and healthcare systems and ensure that it is implemented nationally so that all health care professionals who intend to prescribe and/or dispense PhotoBarr are provided with the following:

- Prescriber guide
- Prescriber slide kit
- Healthcare professionals administration and monitoring guide
- Patient alert card
- Patient guide

The following *key elements* should be included in the educational materials:

Prescriber guide and Prescriber slide kit

- The educational tools are designed to aid physicians in optimising the benefit-risk ratio of porfimer treatment.
- Patients should NOT be treated with porfimer if:
 - they have severe hepatic disease.
 - they have trachea or broncho-oesophageal fistulas.
 - they have suspected erosions of major blood vessels.
- Caution should be exercised if patients have moderate hepatic disease
- Before initiating therapy,
 - The patient should be screened for skin type
 - Patients should be aware of the long half-life of porfimer and that the compound gets activated by light.
 - Patients should avoid being exposed to light for 60-90 days post-exposure.
 - all patients should know that UV blocking is not effective in blocking visible light which activates porfimer.
 - Patients should be aware of potential risk factors (skin phototype and hepatic impairment).
 - Patients should be instructed to seek medical advice if signs/symptoms suggestive of photosensitivity occur during or after therapy with porfimer.

Healthcare professional's administration and monitoring guide

- It is important to follow exactly the correct steps for reconstitution and administration of porfimer.
- It is important to have an appropriate light dose and a proper setting for the laser.
- Any unused product or waste material should be disposed of in accordance with local requirements.
- Healthcare professionals should be aware of side effects that may arise during or shortly after treatment, and how to treat them.
- Patients should be warned of the possibility of long term side effects, especially photosensitivity, and the need to seek medical assistance if they arise.
- Record the patient's skin type and the date of injection on the patient alert card

Patient alert card

- The need to show this card to any doctor treating them

- That PhotoBarr
 - o Remains in your body for 60-90 days after receiving the injection
 - o Is activated by visible light
 - o There is an increased risk of photosensitivity (sensitivity to light)
 - o Exposed skin will become red and cause discomfort in most cases but severe cases of photosensitivity are possible
 - o Commercially available sun blocks are not effective in preventing sensitivity due to light
 - o Photosensitivity can only be prevented by avoiding exposure to the sun for 90 days after receiving the PhotoBarr injection
- You should not be treated with PhotoBarr if you have severe liver disease (eg cirrhosis)
- You should be screened for skin type
- Area in card for physician to record skin type and date of injection.

Patient guide

- Brief background and introduction to Barrett's oesophagus and high grade dysplasia
- What photodynamic therapy is
- Patients should inform their doctor **before** they start treatment if they have severe hepatic disease.
- That PhotoBarr
 - o Remains in your body for 60-90 days after receiving the injection
 - o Is activated by visible light
 - o There is an increased risk of photosensitivity (sensitivity to light)
 - o Exposed skin will become red and cause discomfort in most cases but severe cases of photosensitivity are possible
 - o Commercially available sun blocks are not effective in preventing sensitivity due to light
- Photosensitivity can only be prevented by avoiding exposure to the sun for 90 days after receiving the PhotoBarr injection
- It is important that patients tell their doctor if they get exposed to sunlight after receiving treatment with PhotoBarr.
- There are a number of potential side effects that patients should be aware of.