NO NATURAL RUBBER LATEX:

Natural rubber latex is **not used** in the manufacture of Oyavas®. The different auxiliary materials, bags, filters, hoses, connectors, filling needles, vials and rubber stoppers and other elements and parts that are in contact with the active substance (Bevacizumab) are **not made of natural rubber latex**. Stoppers used for Oyavas® are made of chlorobutyl**.**
Furthermore, Latex, PVC or DEHP are not present on the labels used for MB02. Labels are environmentally friendly and recyclable.

SHELF LIFE & STABILITY IN USE

Oyavas® 100mg/4mL and 400mg/16mL has a shelf life of 30 months (aimed to be extended till 36M, pending completion of ongoing stability studies) when the vial is unopened and stored in approved conditions.

Chemical and physical in-use stability has been demonstrated for 30 days at 2ºC to 8ºC plus an additional 48 hours at temperature not exceeding 30°C in sodium chloride 9 mg/mL (0.9%) solution for injection. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Additional in-use stability study performed for Oyavas® (4mL and 16mL vials) has demonstrated chemical and physical stability of residual volumes of Oyavas® solution in vials up to 180h at 2°C to 8°C when conserved. When conserving opened vials, aseptic conditions should be respected and are the responsibility of the user. This study is not published, and not included in the SmPC/ MB02 Dossier.

- Store in a refrigerator (2°C - 8°C).
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.

DENSITY

The density of MB02 concentrate for solution for infusion is 1.033g/mL.

OVERFILL

An overfill is used for Oyavas®. A target fill volume of 4.30 mL and 16.60 mL is applied to the 100mg/4mL and the 400mg/16mL presentations respectively (reference EPAR scientific assessment 2021).

PACKAGING

We have received assurances from our suppliers that all substances contained in raw materials supplied for packaging were registered or pre-registered in accordance with REACH (unless the substances in question are exempt from registration). They also notify us of the presence of SVHC in their raw materials above the set limit of 0.1% by weight.

Packaging products do not contain any substances classed as CMR (carcinogenic, mutagenic, reprotoxic) of category 1A, 1B, or 2, any substances classed as nanomaterials or from the prohibited substances list.

Packaging does not process or intentionally add during manufacture of its products any substances based on:

- Lead
- Cadmium
- Mercury or
- Hexavalent Chromium

BOXES

All our paperboards are made from fresh fibers, which can be traced back to their source in sustainably managed northern forests.

The product has been tested by an independent laboratory for suitability for food contact and compliance with the regulations and recommendations, taking also into consideration the declarations of compliance provided by our raw materials and additives suppliers and additional information obtained on a confidential basis

Boxes have been tested and risk assessment was performed for elemental impurities of Class 1 (As, Pb, Cd, Hg) and Class 2A (V, Co, Ni) according to ICH Q3D guideline on elemental impurities and no such impurities would require further controls for primary or secondary pharmaceutical product packaging.

Boxes are manufactured from fresh fibers and therefore there is less risk of non-intentionally added substances (NIAS) such as traces of printing inks or mineral oils. The supplier evaluates all used raw materials and conducts internal risk assessment based on the supplier information.

LEAFLETS

Our leaflets do not contain latex, PVC and DEHP; and that they are recyclable and environmentally friendly.