



**EXTRACAP® non gamma<sub>2</sub> (I)**  
**EXTRACAP® non gamma<sub>2</sub> (II)**  
**Encapsulated copper rich alloy, without gamma<sub>2</sub> phase**  
**and mercury for amalgam fillings**

## **COMPOSITION**

1 g of alloy in powder contains:

Silver	500 mg
Tin	299 mg
Copper	201 mg
1 g mercury 99.9% contains:	1000 mg

## **CHARACTERISTICS**

Extracap® non gamma<sub>2</sub> (I) and (II) capsules contain amalgam alloy with 50% of silver, 20.1% of copper and a corresponding amount of mercury. The alloy does not contain zinc. It belongs to the group of copper rich amalgam alloys, without gamma<sub>2</sub> phase. It is easily prepared in tritulators.

Physical properties:

Resistance to pressure – after 1 h:	not less than 100 MPa
Compression strength – after 24 h:	not less than 350 MPa
Particle size:	not more than 100 µm
Creep:	not more than 2%
Dimensional changes:	-0.10% to +0.15%

## **INDICATIONS**

Permanent amalgam fillings for cavities in posterior teeth.

## **CONTRAINDICATIONS**

Hypersensitivity to mercury.

## **PRECAUTIONS**

The filling of the silver alloy for amalgam and mercury in the protective foil in the capsule reduces the risk from the known toxic effect of mercury.

Control if the capsule is properly closed, prior to trituration.

Avoid contact of the amalgam mixture with eyes, skin and clothing. When working, be sure to use protective gloves and goggles that fit well.

## **SPECIAL WARNINGS**

### **Hazard statements:**

H330: Fatal if inhaled.

H360D: May damage the unborn child.

H372: Causes damage to organs through prolonged or repeated exposure.

H410: Very toxic to aquatic life with long-lasting effects.

### **Precautionary statements:**

P202: Do not handle until all safety precautions have been read and understood.

P273: Avoid release to the environment.

P304 + P340: If inhaled: Remove person to fresh air and keep comfortable for breathing.

P308 + P313: If exposed: Call a National Poison Center or doctor/physician.

P403 + P233: Store in a well ventilated place. Keep container tightly closed.

P501: Dispose of contents / container in accordance with local regulation.

## **DOSAGE AND APPLICATION**

- For amalgam fillings for small and medium cavities use Extracap® non gamma<sub>2</sub> (I) red capsules (alloy weight 0.360 g and mercury weight 0.400 g).

- For amalgam fillings for large cavities use Extracap® non gamma<sub>2</sub> (II) blue capsules (alloy weight 0.540 g and mercury weight 0.600 g).

The capsules may be placed immediately in one of the automatic mixers and triturated.

Mixers should have 4500 rotations per minute.

Trituration time: 9-15 seconds (in Silamat).

Working time: 4 to 9 minutes.

Open the capsule manually by twisting and pulling the cap at the same time. Take care not to spill the contents of the capsule when opening.

Remove the plastic bag containing the mercury in the capsule prior to use.

Place the amalgam mixture into the cavity with a carrier, in small portions and condense well with a compactor with a round tip.

The finishing and polishing of fillings may be performed after 48 hours.

## **NOTE**

Only for professional use.

## **ADVERSE EFFECTS**

In rare cases, patients may suffer from local reactions to amalgam such as: burning sensation of the oral mucosa, lichenoid changes and granulomatous lesions of the orofacial region.

In case the therapist's hands come into direct contact with the amalgam mixture, allergic or irritant dermatitis may appear.

If these or other adverse effects which are not listed above occur, contact your doctor.

## **STORAGE**

Store in the original package at temperature up to 25°C.

## **SHELF LIFE**

5 years.

Do not use the medical device after the expiry date indicated on the package.

Any used or unused product which is beyond the expiry date should be handled in accordance with the applicable legal regulations.

## **PACKAGING**

Separately:

25 capsules of Extracap® non gamma<sub>2</sub> (I)

25 capsules of Extracap® non gamma<sub>2</sub> (II)

50 capsules of Extracap® non gamma<sub>2</sub> (I)

50 capsules of Extracap® non gamma<sub>2</sub> (II)

Combined 50 capsules of Extracap® non gamma<sub>2</sub> (I) and 50 capsules of Extracap® non gamma<sub>2</sub> (II)

Decision No:

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