



SAFARGAM Plus



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INSTRUCTION FOR USE:

The SAFARGAM Plus is high copper alloy for dental amalgam without gamma-2 phase. The alloy is free of zinc. A type of powder: filings. It is supplied in dosed self-activating capsules or as powder in bulk. Amalgam is safe in examination by magnetic resonance imaging. For single use.



Indication:

Fillings for dental restorations.

Contraindication:

In case of hypersensitivity or allergic reaction to any of the components of dental amalgam.
For milk teeth, for children under 15 years of age. For pregnant or nursing women.

ACCORDING TO ISO 24234 AND ISO 13897 STANDARDS

Chemical composition (mass %): Ag 50% Sn 30% Cu 20%

Nominal mass alloy : mercury ratio: 1 : 1,1

Delivered amount – powder in bulk:

50, 100, 250, 500, 1000, 5000 g

Delivered form of capsules:

50 capsules

Capsule length:

32 mm

Max. diameter of capsules:

13,2 mm

Filling of capsules and net mass of 50 pcs in the package:

1: 350 mg alloy and 400 mg Hg,

net: 17,5 g alloy and 20 g Hg

2: 525 mg alloy and 600 mg Hg,

net: 26,25 g alloy and 30 g Hg

3: 700 mg alloy and 800 mg Hg,

net: 35,0 g alloy and 40 g Hg

Capsules contain dental mercury according to ISO 24234.

Storage conditions:

at temperature no higher than 28°C,
in clean surroundings without chemical vapours.



Shelf life: when stored properly until expiring date (5 years).

Specified application purpose: The alloy is used for preparing dental amalgam as tooth filling after mixing with dental mercury with using amalgamators.

Amalgam appearance: The ready-mixed amalgam is a coherent plastic mass with shiny surface.

Time of plasticity: 5 minutes

Mixing time for powder in bulk:

Amalgamator 1 dosage 2-3 dosage

Dentomax/Duomat 45s 50s

Mixing Boy MLW 9002 55s 60s

1 dosage of alloy + mercury (1,1:1) is approximately 600 mg

Mixing time for capsules:

Type of amalgamator	Capsule		
	1	2	3
Mixing Boy MLW 9002: (3200 rpm)	40s	30s	30s
Linea TAC400M: (4200 rpm)	12s	12s	12s
3M Espe CapMix: (4650 rpm)	7s	8s	9s

Warning: When not comply with recommended mixing conditions producer does not guarantee product properties.

Processing instruction:

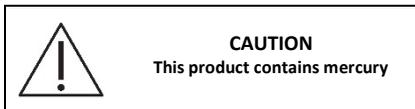
Amalgam mixing: Respect the amalgamator manufacturer's instructions or our setting recommendations during a mechanical mixing. The given mixing recommendation should first be tested or altered where necessary in accordance with your own needs after each amalgamator replacement. In case that amalgamator is not mentioned in these instructions the amalgam mixing parameters have first to be tested and set. The settings have to be selected in respect to appearance of the ready mixed amalgam that must have

a plastic and smooth consistency convenient for the dentist. The mixed up amalgam should form a coherent plastic mass with shiny surface, without any coatings. After the amalgam is mixed up open the plastic capsule on one side of the capsule.

If amalgam consistency does not comply correct the amalgamator settings: Reduction of mixing time and reduction of frequency of the mixing leads to the wetter consistency and vice versa. A change of amalgam consistency is usually connected with a change of time of plasticity – wetter amalgam has longer time of plasticity and vice versa.

Condensing and modelling: The mixed up amalgam is plastic, glossy and smooth, well-condensing. Fill the amalgam into the cavity corners with a small flat-fronted tool. Apply the filling occlusion layer by layer, using increasingly bigger tools. Remove from the filling's surface the mercury-rich amalgam layer each time before applying the new one. Make the filling with a surplus. It can be finished to an anatomical shape with the sharp modelling tools after 6-9 minutes.

Polishing: The surface of the filling should be polished to a high degree of gloss after 24 hours, using the Arkansas stone and rubber rotating tools.



Pictogram(s):



GHS06



GHS08



GHS09

Signal word: Danger

Hazard statement(s):

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 statement(s):

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P310 Immediately call a POISON CENTER or doctor/physician.

P405 Store locked up.

P502 Refer to manufacturer/ supplier for information on recovery/recycling

Precautionary notes:

Properties changes:

Do not use dental amalgam in case of incorrect consistency of amalgam.

Effect of mercury on metals: Mercury corrodes and embrittles particular metals and their alloys. Avoid unnecessary contact between mercury and those metals.

Spillages: Mercury presents health hazard if handled incorrectly. Mercury is toxic by vapour inhalation and the effect is cumulative. Spillages of mercury should be removed immediately, including from places which are difficult to access. Use a plastic syringe to draw it up. Smaller quantities can be covered by sulfur powder and removed. Individual small droplets can be picked up by tin foil (Sn) and removed. Avoid inhalation of the vapour. During and after clean-up thoroughly ventilate the area where the spill has occurred.

Moisture contamination: If the moisture is introduced into amalgam before it has set properties such as strength and corrosion resistance can be affected adversely. The alloy does not contain zinc. This is why there is no risk of any excessive (delayed) expansion of the amalgam. Use a dry field whenever is possible despite that.

Waste disposal / Disposal of used capsules:

Waste materials and all primary containers that have held mercury shall be disposed of following appropriate management practice. Used capsules and waste materials have to be handled as the very dangerous wastes - they contain remainders of dangerous matters - mercury. Dispose of used capsules in accordance with national regulations.