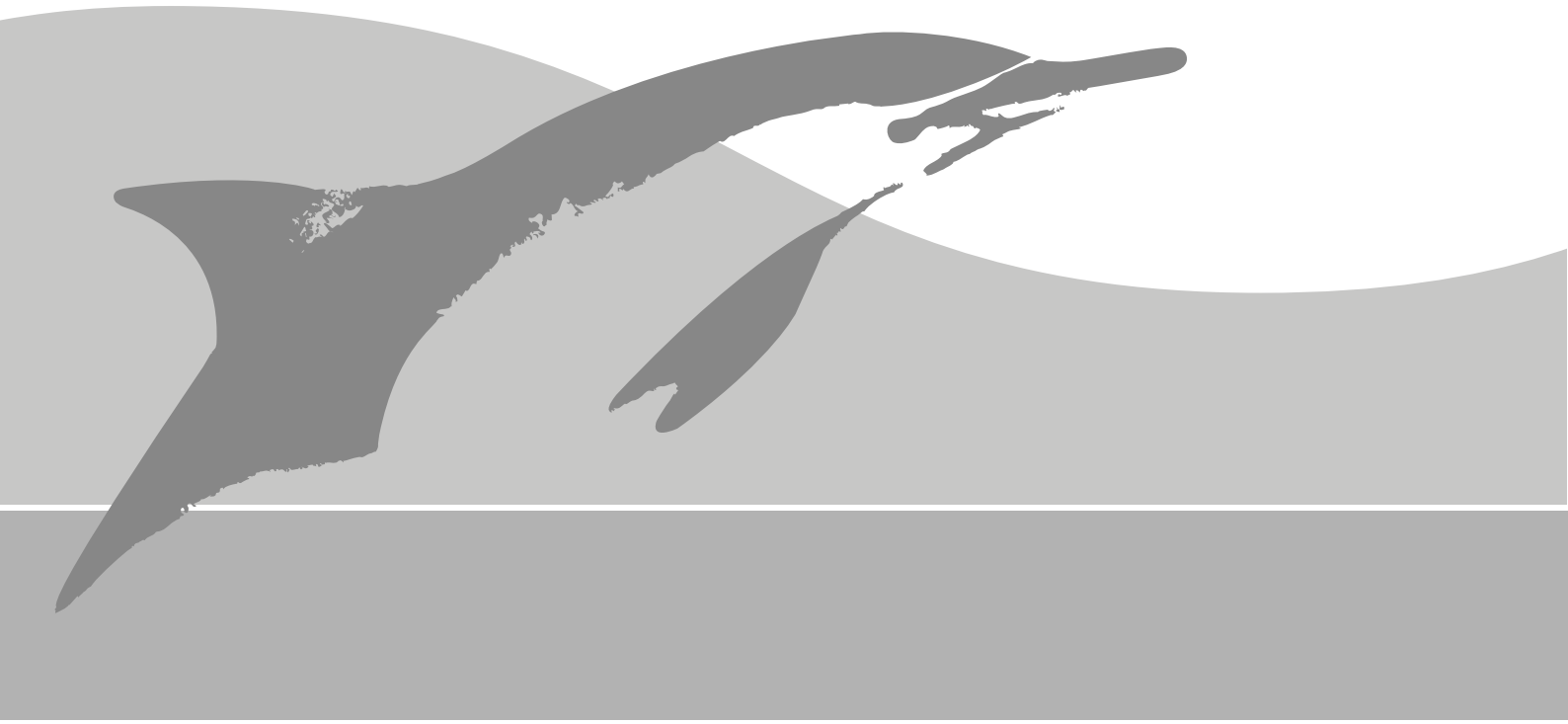
Heraeus

Medical

COPAL®

COPAL® G+V

Patient Information
(Only applicable in Australia!)



EN (AU)

COPAL®

Patient Information

Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare professional (doctor or surgeon) if you need more information or advice.
- If you experience any side effects, talk to your healthcare professional. See section 4.

What is in this leaflet?

1. What COPAL® G+V is and what it is used for
2. What you need to know about COPAL® G+V
3. How to use COPAL® G+V
4. Side effects and residual risks
5. Composition and other information
6. Manufacturer

1. What COPAL® G+V is and what it is used for

COPAL® G+V is a bone cement based on a biologically safe material called polymethyl methacrylate (PMMA).
The bone cement is used in adults such as elderly patients with risk factors for periprosthetic joint infection to anchor total or partial joint endoprostheses by attaching the endoprosthesis firmly and stably to the bone. Endoprostheses are medical devices that are used to replace parts of the inside of your body such as hip, knee or shoulder joints.

2. What you need to know about COPAL® G+V

Ensure that your healthcare professional is aware of any allergies and medical conditions that you may have.

Warnings and precautions
COPAL® G+V contains gentamicin and vancomycin, two antibiotics. It is most unlikely that this bone cement causes gentamicin or vancomycin overdosage, because the gentamicin and vancomycin it carries mostly stay in the area where the cement is applied. They only lead to low (equal to or less than 1 µg/mL) and short-lived levels of antibiotic in the rest of the body.

Both gentamicin and vancomycin can potentially cause side effects in patients with impaired renal function, patients who are at risk of developing renal failure, or in patients who simultaneously receive drugs which affect the kidneys. In these cases, your healthcare professional may advise to monitor your blood levels of the antibiotic, electrolytes or renal function.

Other medicines and **COPAL® G+V**
Tell your healthcare professional if you are taking, have recently taken or might take any other medicines including: antibiotics, diuretics, muscle relaxants and chemotherapy drugs.

3. How to use COPAL® G+V

The bone cement is going to be applied by your healthcare professional during surgery in accordance with instructions for use intended for healthcare professionals.

During your surgery your healthcare professional takes care of the following aspects:
- Your bone where the bone cement will be applied will be carefully cleaned, aspirated, and dried just before the bone cement is placed.
- Your prosthesis will be put in place and held until the bone cement has set completely.
- During and immediately after the bone cement is applied, your health professionals will monitor your blood pressure, pulse, and breathing carefully for the early detection and treatment of cardiovascular adverse events that may occur such as low blood pressure and cardiac arrest. The blood pressure of some patients has decreased between 10 and 165 seconds after application of bone cement and it has lasted from 30 seconds to 5 or more minutes. However, consequences such as cardiac arrest are only reported in very few cases.

Interference with diagnostic tests
It is safe to have magnetic resonance tests with **COPAL® G+V**. However, your ability to have magnetic resonance tests may be affected by the composition of the prosthesis you receive together with the bone cement.

Preventative examination
You need to make appointments for check-ups at regular intervals once you have received **COPAL® G+V**. Your healthcare professional will be able to recognize and treat any complications, some of which may occur without you noticing.

Discomfort or complications
Contact your healthcare professional immediately if you experience any discomfort or complications, e.g., impaired mobility in the joint area, reddening, pain, fatigue, or fever.
Consult your healthcare professional before undertaking any new or unusual activities.

Expected lifetime
There is no general factor influencing the lifetime of **COPAL® G+V**. The general provisions for the prosthesis they are used to anchor also apply to bone cements. The actual lifetime of the bone cement can be influenced by factors such as your medical situation and your lifestyle.

4. Side effects and residual risks

In some cases, the following side effects that are typical for joint surgery may occur, and possibly require further surgical treatment: allergic reactions against components of the prosthesis or bone cement, loosening of the endoprosthesis, and endoprosthesis dislocation. Typically, these complications are accompanied by nonspecific symptoms such as pain, fatigue, or fever.

The following residual risks could arise due to shortcomings of preventative measures during surgery: infection; need for revision of the prosthesis; toxic, allergic or anaphylactic shock.

Please contact your healthcare professional if you have any questions.

Reporting of side effects or serious incidents
If you experience any of these side effects, or if you notice any side effects not listed in this leaflet, contact your healthcare professional immediately.

Any serious incident that occurs in relation to the bone cement should be reported to Heraeus Medical GmbH (hm.vigilance.medical@heraeus.com) and to the Therapeutic Goods Administration (https://www.tga.gov.au).

5. Composition and other information

COPAL® G+V contains:

COMPOSITION	
Powder:	
PMMA copolymer	78 %
zirconium dioxide	14 %
benzoyl peroxide	1 %
gentamicin sulfate	2 %
vancomycin hydrochloride	5 %
Liquid:	
methyl methacrylate	98 %
N, N-dimethyl-p-toluidine	2 %

The data is rounded

Other constituents:
- Powder: chlorophyll-copper-complex (E141)
- Liquid: chlorophyll-copper-complex (E141), hydroquinone

Traces of histamine may be present in these bone cement. **COPAL® G+V** does not contain a radiation source.

No manufacturing residuals that could pose a risk to the patient have been found.

Be aware that the composition table shows the constituents before mixture of the bone cement components. The methyl methacrylate will be consumed during setting of the bone cement.

6. Manufacturer

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