

PerOssal®

Product Guide





Note

*The dosage recommendation relates to the in vitro results, as well as to the results obtained within the scope of clinical testing. The treating physician is responsible for the final decision regarding the type and quantity of the corresponding antibiotic. The contraindications of the applied antibiotic have to be considered.

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Package sizes & bulk volume

PerOssal® is indicated for filling or reconstruction of bone defects and is available in the following package sizes:

1x6

6 pellets \triangleq 1.5 cm³ bulk volume



2x6

12 pellets \triangleq 3.0 cm³ bulk volume



1x50

50 pellets \triangleq 12.5 cm³ bulk volume



Note:
1 pellet \triangleq 0.25 cm³

Fluid uptake

PerOssal® are cylindrical pellets measuring 6 mm x 6 mm, with one spherical and one flat end. PerOssal® has a porous structure that allows the safe absorption of aqueous solutions. The fluid uptake is 0.08 ml/pellet.

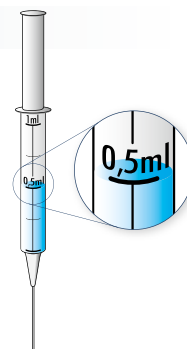


1x6

6 pellets can absorb 0.48 ml fluid



**fluid uptake
0.48 ml**

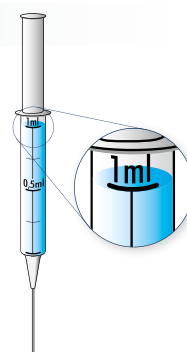


2x6

12 pellets can absorb 0.96 ml fluid

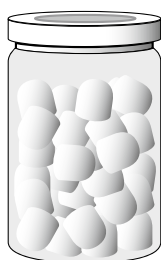


**fluid uptake
0.96 ml**

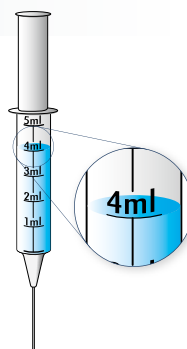


1x50

50 pellets can absorb 4 ml fluid



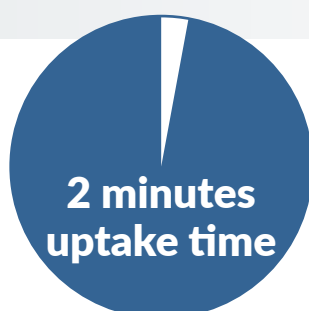
**fluid uptake
4 ml**



Preparation time

PerOssal® is »Ready to Use« as soon as the fluid is completely absorbed (after approx. 2 minutes).

2 minutes fluid uptake time



Dosage recommendation* for antibiotic load based on antibiotic products available in the market

Antibiotic solution

Various antibiotics are provided as solutions and are therefore ready to use. According to the dosage recommendations from the manufacturer (see IFU) the antibiotic solution can be used immediately for drenching of the pellets.

For instance:



Gentamicin

**40
mg/ml**



Tobramycin

**40
mg/ml**

Antibiotic powder

Some antibiotics are provided as powder. As PerOssal® is a carrier for fluid substances, the powder has to be dissolved in a fluid** before drenching of the pellets. Please follow the Instructions for Use enclosed with the antibiotic powder.

For instance:



Vancomycin

**100
mg/ml**



Rifampicin

**60
mg/ml**

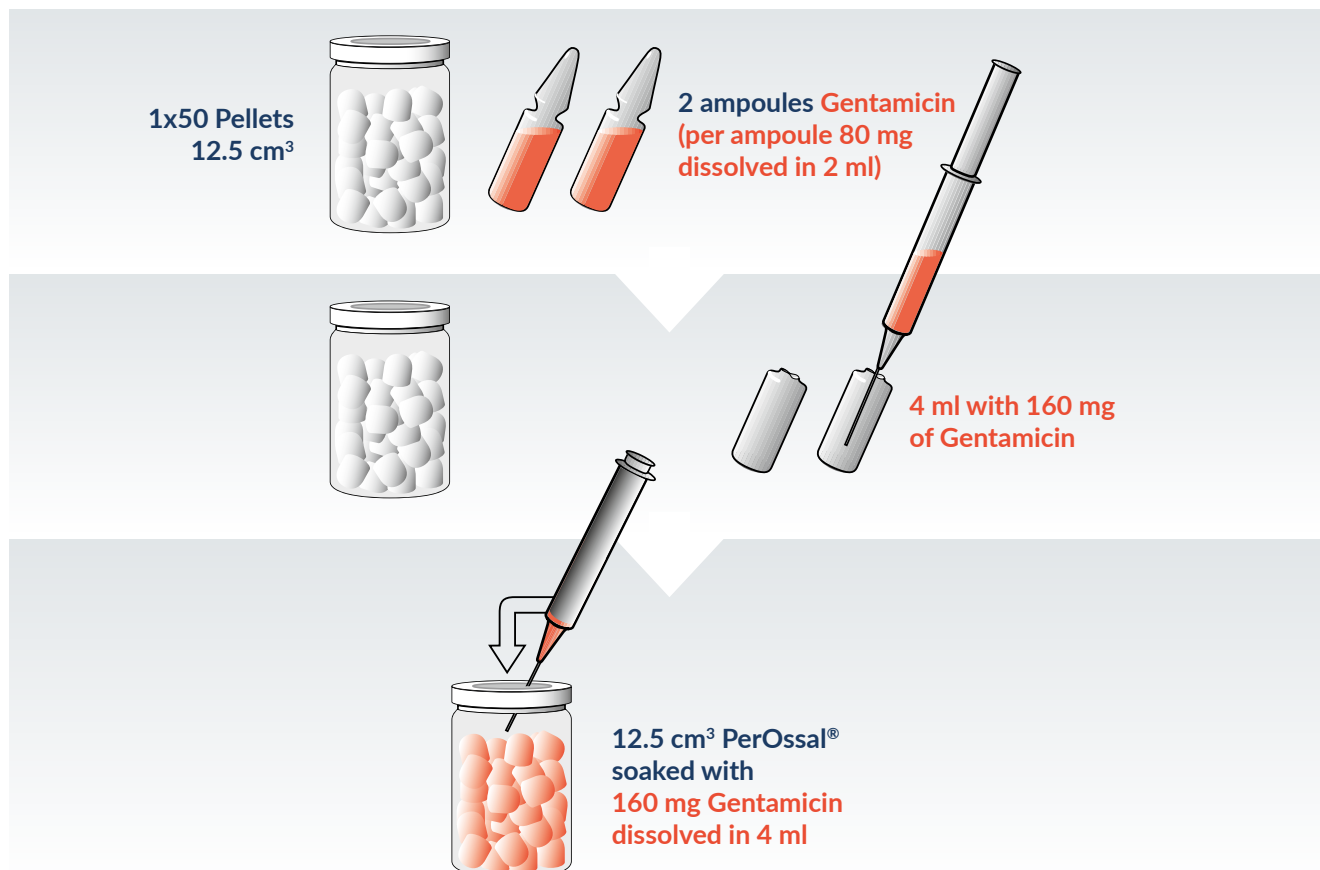
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**e.g. sterile water for injection purposes (aqua ad iniectionem)

Antibiotic solution (Single application)

Dosage recommendation*

Example: **Gentamicin** with PerOssal® 1x50



Gentamicin

	1x50 pellets	2x50 pellets	3x50 pellets
Bulk volume	12.5 cm ³	25 cm ³	37.5 cm ³
Amount of antibiotic	160 mg	320 mg	480 mg
Volume of antibiotic solution	4 ml	8 ml	12 ml

**40
mg/ml**

Tobramycin

	1x50 pellets	2x50 pellets	3x50 pellets
Bulk volume	12.5 cm ³	25 cm ³	37.5 cm ³
Amount of antibiotic	160 mg	320 mg	480 mg
Volume of antibiotic solution	4 ml	8 ml	12 ml

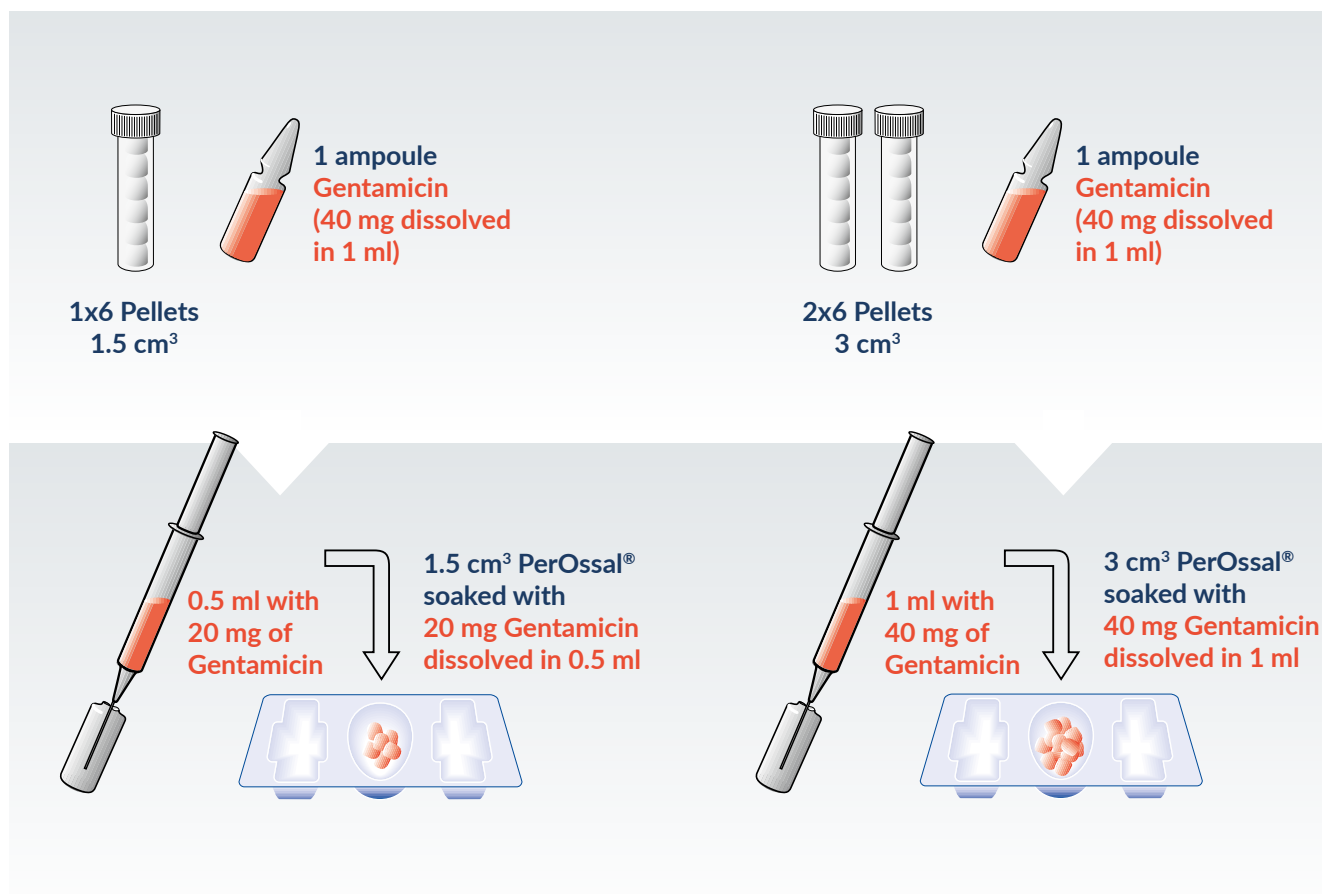
**40
mg/ml**



Antibiotic solution (Single application)

Dosage recommendation*

Example: Gentamicin with PerOssal® 1x6 or 2x6



Gentamicin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³
Amount of antibiotic	20 mg	40 mg	60 mg	80 mg
Volume of antibiotic solution	0.5 ml	1 ml	1.5 ml	2 ml

40
mg/ml

Tobramycin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³
Amount of antibiotic	20 mg	40 mg	60 mg	80 mg
Volume of antibiotic solution	0.5 ml	1 ml	1.5 ml	2 ml

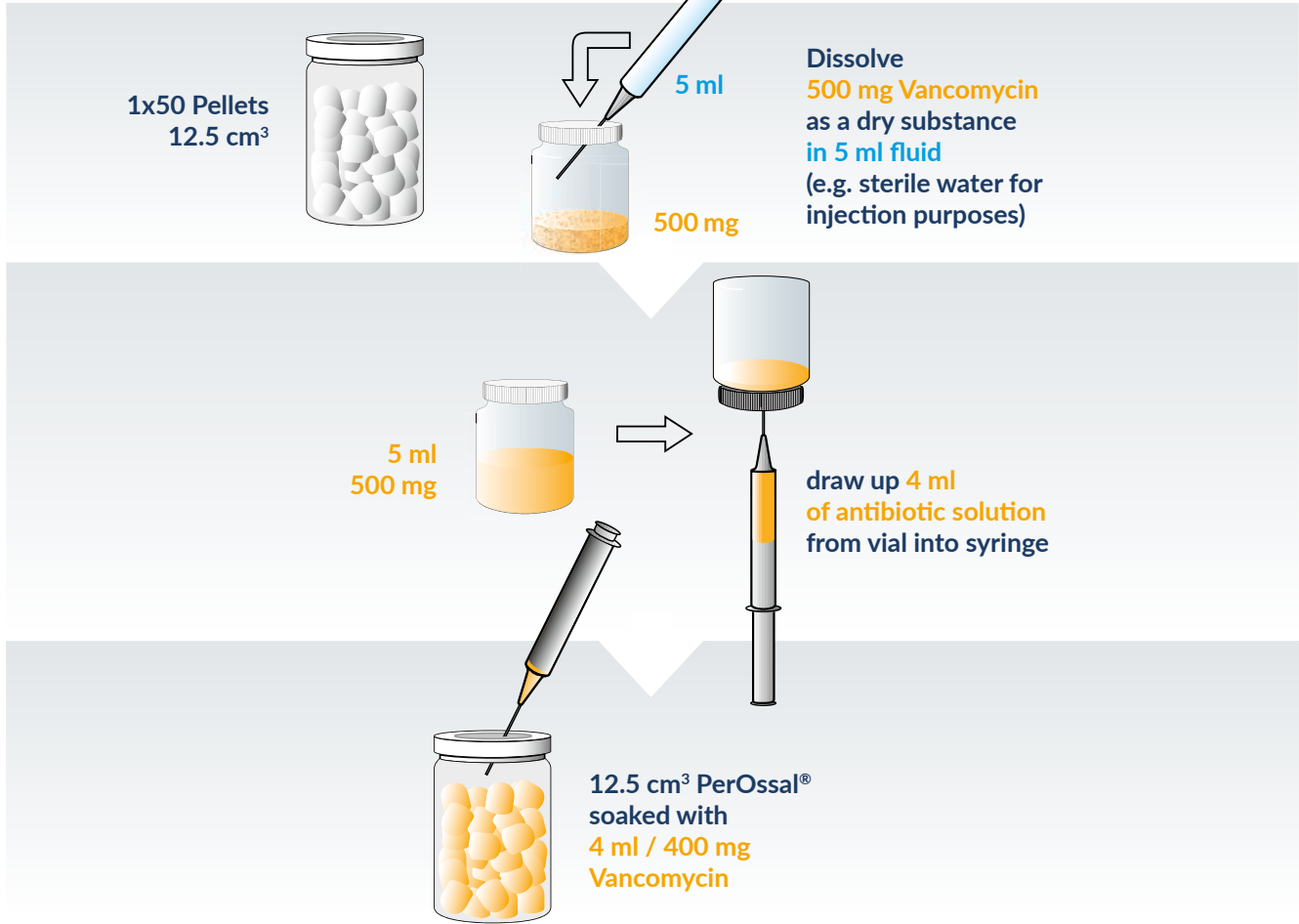
40
mg/ml



Antibiotic powder (Single application)

Dosage recommendation*

Example: Vancomycin with PerOssal® 1x50



Vancomycin

	1x50 pellets	2x50 pellets
Bulk volume	12.5 cm ³	25 cm ³
Amount of antibiotic	400 mg	800 mg
Volume of antibiotic solution	4 ml	8 ml

100
mg/ml

Vancomycin

	1x50 pellets	2x50 pellets	3x50 pellets	4x50 pellets	5x50 pellets
Bulk volume	12.5 cm ³	25 cm ³	37.5 cm ³	50 cm ³	62.5 cm ³
Amount of antibiotic	200 mg	400 mg	600 mg	800 mg	1000 mg
Volume of antibiotic solution	4 ml	8 ml	12 ml	16 ml	20 ml

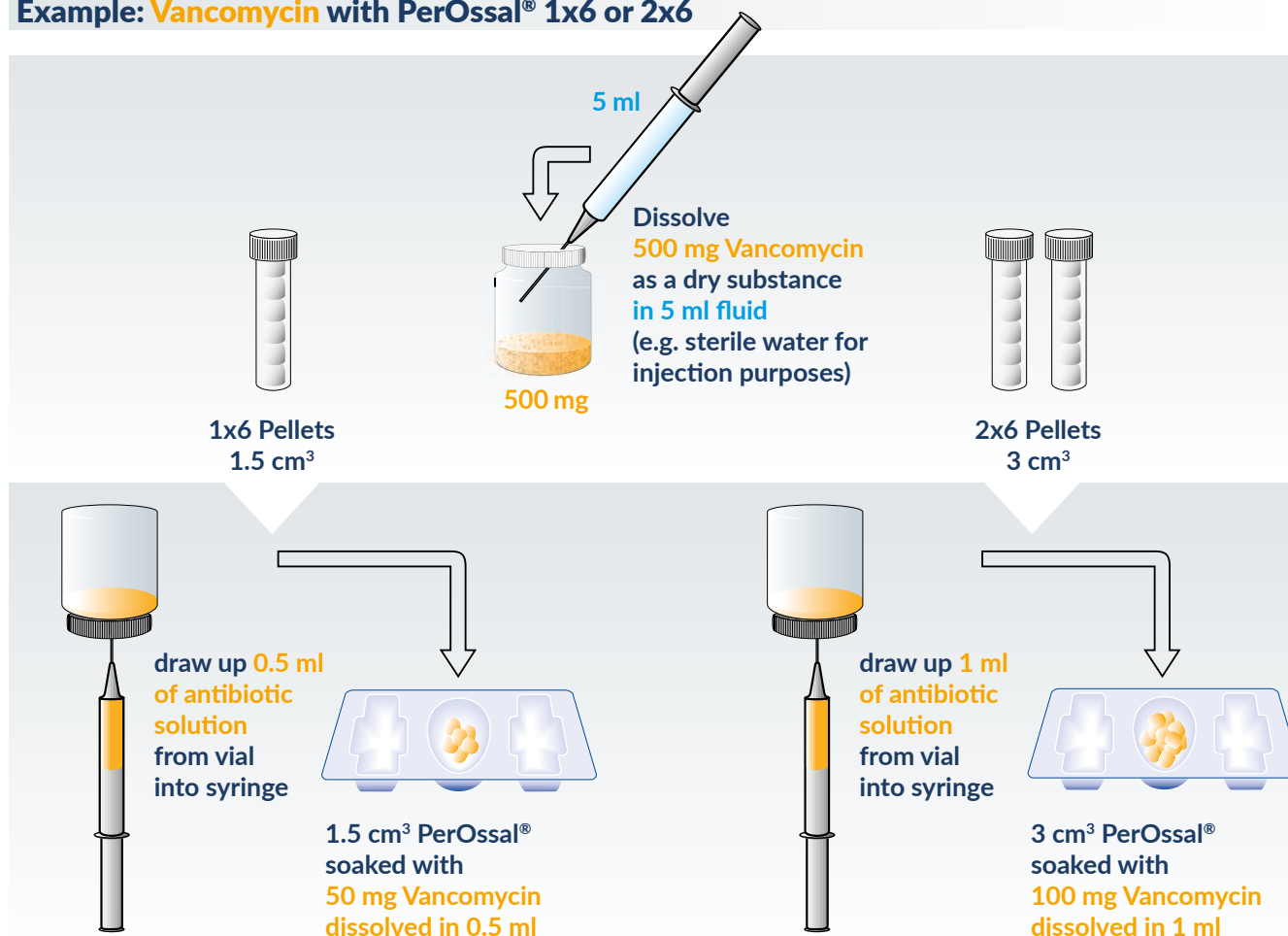
50
mg/ml



Antibiotic powder (Single application)

Dosage recommendation*

Example: Vancomycin with PerOssal® 1x6 or 2x6



Vancomycin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³
Amount of antibiotic	50 mg	100 mg	150 mg	200 mg
Volume of antibiotic solution	0.5 ml	1 ml	1.5 ml	2 ml

**100
mg/ml**

Vancomycin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³
Amount of antibiotic	25 mg	50 mg	75 mg	100 mg
Volume of antibiotic solution	0.5 ml	1 ml	1.5 ml	2 ml

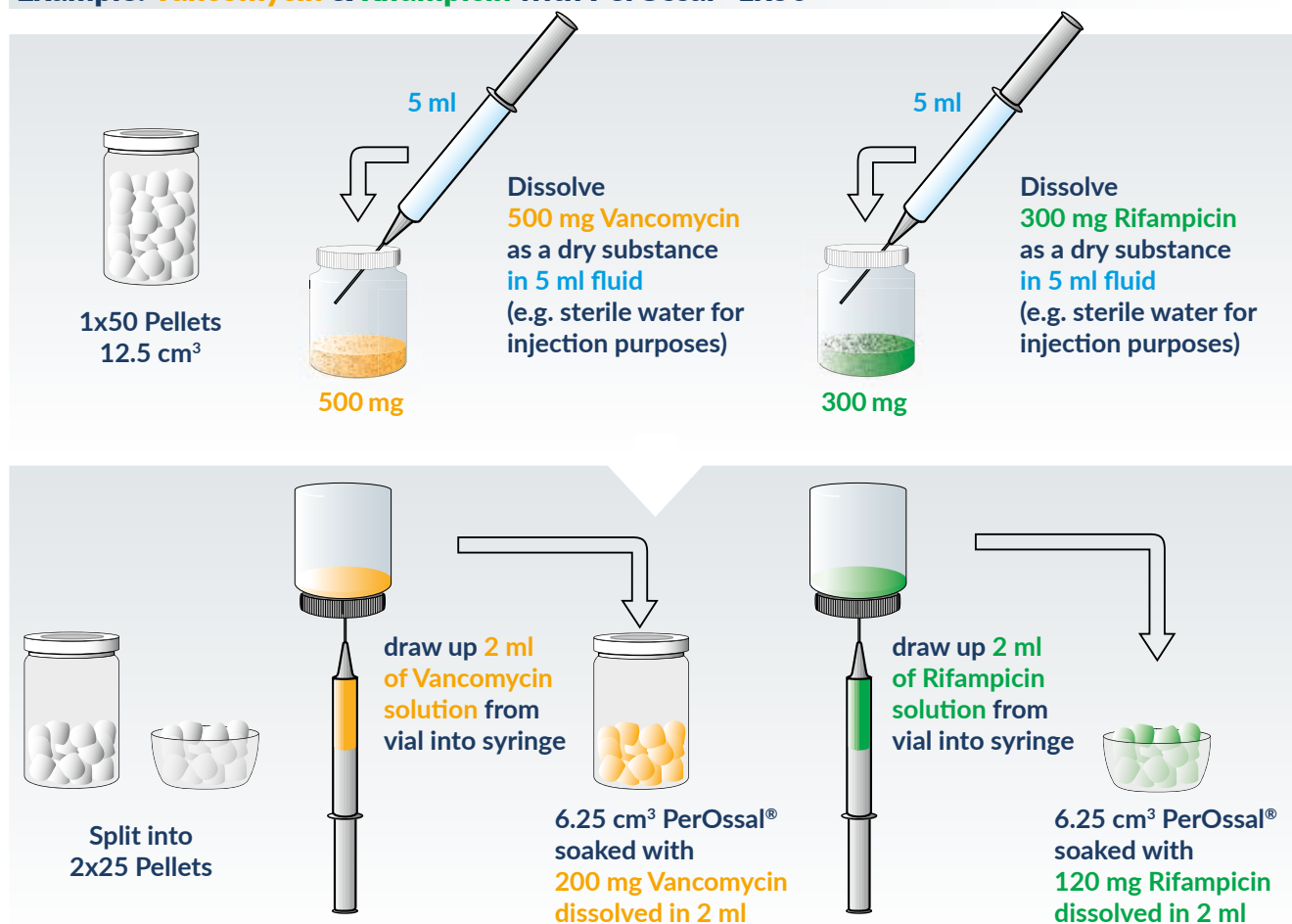
**50
mg/ml**



Antibiotic powder (Combined application)

Dosage recommendation*

Example: Vancomycin & Rifampicin with PerOssal® 1x50



Vancomycin & Rifampicin

	1x50 pellets	2x50 pellets	3x50 pellets	4x50 pellets	5x50 pellets
Bulk volume	12.5 cm ³	25 cm ³	37.5 cm ³	50 cm ³	62.5 cm ³
Amount of Vancomycin	200 mg in 2 ml on 25 pellets	400 mg in 4 ml on 50 pellets	400 mg in 4 ml on 50 pellets	800 mg in 8 ml on 100 pellets	800 mg in 8 ml on 100 pellets
Amount of Rifampicin	120 mg in 2 ml on 25 pellets	240 mg in 4 ml on 50 pellets	480 mg in 8 ml on 100 pellets	480 mg in 8 ml on 100 pellets	720 mg in 12 ml on 150 pellets

100
mg/ml

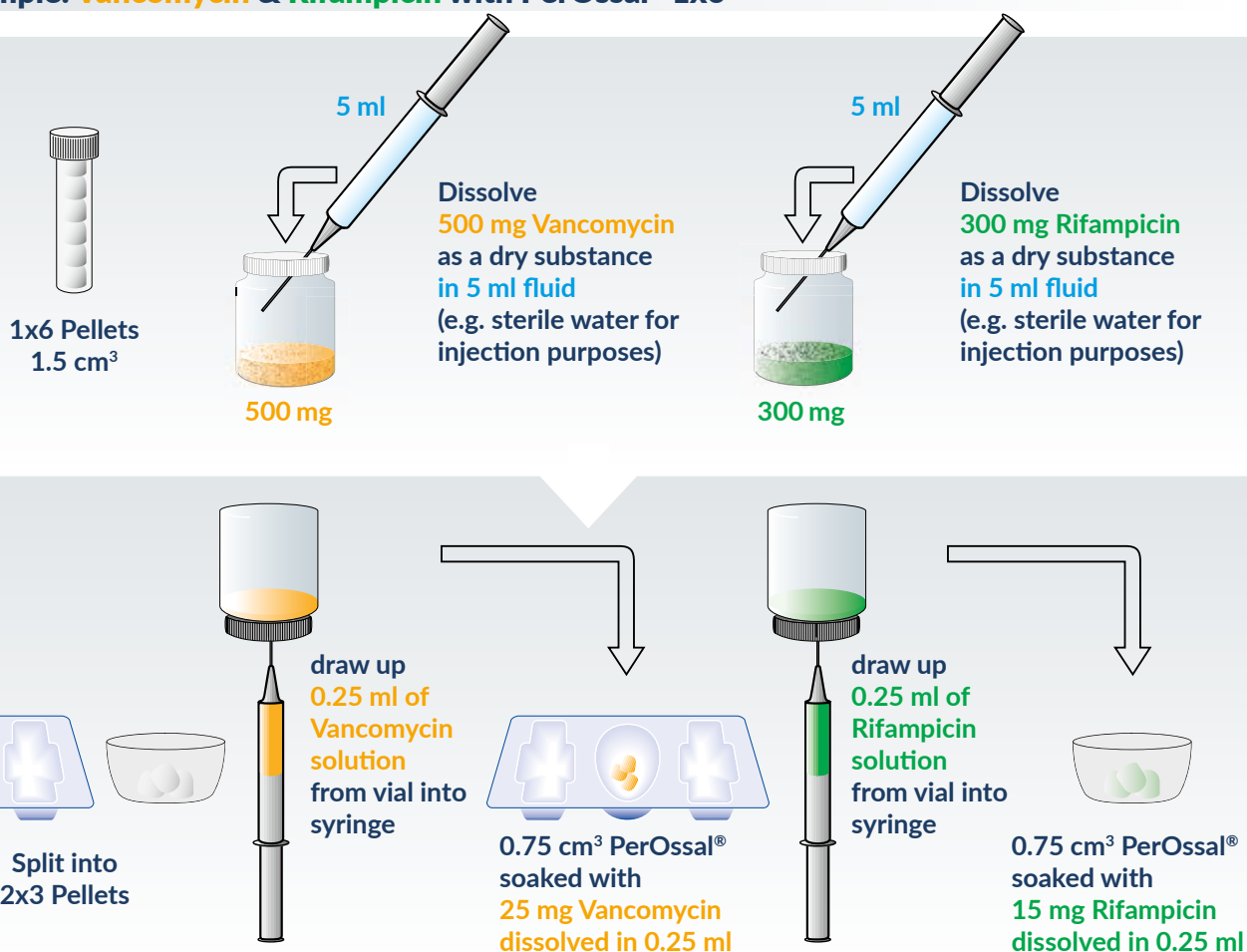
60
mg/ml



Antibiotic powder (Combined application)

Dosage recommendation*

Example: Vancomycin & Rifampicin with PerOssal® 1x6



Vancomycin & Rifampicin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets	5x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³	7.5 cm ³
Amount of Vancomycin	25 mg in 0.25 ml on 3 pellets	50 mg in 0.5 ml on 6 pellets	75 mg in 0.75 ml on 9 pellets	100 mg in 1 ml on 12 pellets	125 mg in 1.25 ml on 15 pellets
Amount of Rifampicin	15 mg in 0.25 ml on 3 pellets	30 mg in 0.5 ml on 6 pellets	45 mg in 0.75 ml on 9 pellets	60 mg in 1 ml on 12 pellets	75 mg in 1.25 ml on 15 pellets

100 mg/ml

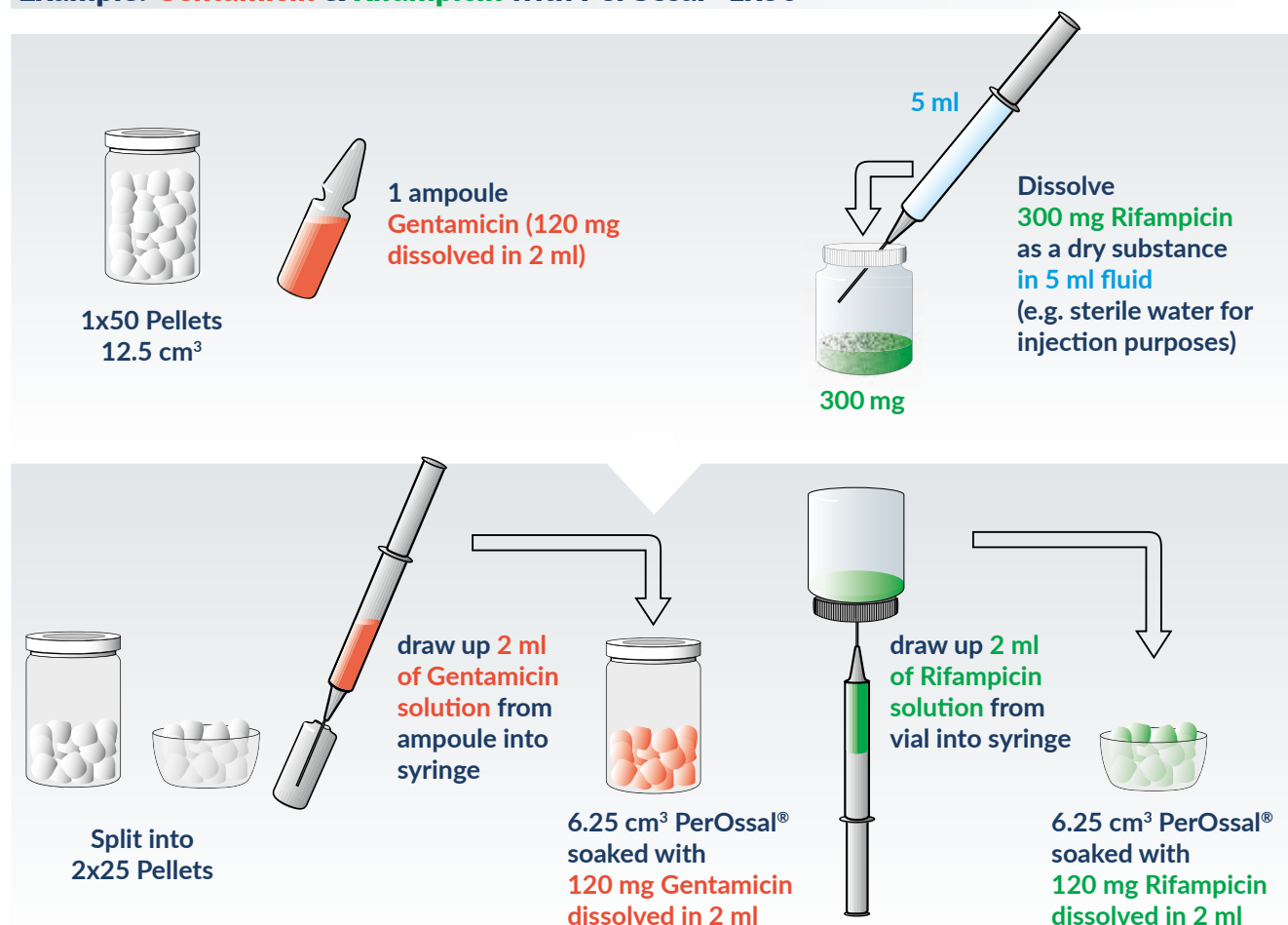
60 mg/ml



Antibiotic solution & powder (Combined application)

Dosage recommendation*

Example: Gentamicin & Rifampicin with PerOssal® 1x50



Gentamicin & Rifampicin

	1x50 pellets	2x50 pellets	3x50 pellets	4x50 pellets	5x50 pellets
Bulk volume	12.5 cm ³	25 cm ³	37.5 cm ³	50 cm ³	62.5 cm ³
Amount of Gentamicin	120 mg in 2 ml on 25 pellets	240 mg in 4 ml on 50 pellets	240 mg in 4 ml on 50 pellets	480 mg in 8 ml on 100 pellets	480 mg in 8 ml on 100 pellets
Amount of Rifampicin	120 mg in 2 ml on 25 pellets	240 mg in 4 ml on 50 pellets	480 mg in 8 ml on 100 pellets	480 mg in 8 ml on 100 pellets	720 mg in 12 ml on 150 pellets

60 mg/ml

60 mg/ml



Antibiotic solution & powder (Combined application)

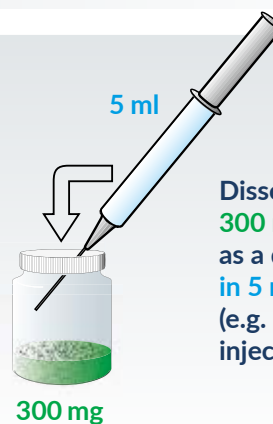
Dosage recommendation*

Example: Gentamicin & Rifampicin with PerOssal® 1x6

1x6 Pellets
1.5 cm³



1 ampoule
Gentamicin (120 mg
dissolved in 2 ml)



Dissolve
300 mg Rifampicin
as a dry substance
in 5 ml fluid
(e.g. sterile water for
injection purposes)

300 mg

Split into
2x3 Pellets



draw up 0.25 ml
of Gentamicin
solution from
ampoule into
syringe

0.75 cm³ PerOssal®
soaked with
15 mg Gentamicin
dissolved in 0.25 ml



draw up
0.25 ml of
Rifampicin
solution
from vial into
syringe

0.75 cm³ PerOssal®
soaked with
15 mg Rifampicin
dissolved in 0.25 ml

Gentamicin & Rifampicin

	1x6 pellets	2x6 pellets	3x6 pellets	4x6 pellets	5x6 pellets
Bulk volume	1.5 cm ³	3 cm ³	4.5 cm ³	6 cm ³	7.5 cm ³
Amount of Gentamicin	15 mg in 0.25 ml on 3 pellets	30 mg in 0.5 ml on 6 pellets	45 mg in 0.75 ml on 9 pellets	60 mg in 1 ml on 12 pellets	75 mg in 1.25 ml on 15 pellets
Amount of Rifampicin	15 mg in 0.25 ml on 3 pellets	30 mg in 0.5 ml on 6 pellets	45 mg in 0.75 ml on 9 pellets	60 mg in 1 ml on 12 pellets	75 mg in 1.25 ml on 15 pellets

60
mg/ml

60
mg/ml

References

- [1] Rauschmann et al. (2005), **Nanocrystalline hydroxyapatite and calcium sulphate as biodegradable composite carrier material for local delivery of antibiotics in bone infections**, Biomaterials. 26(15):2677-2684.
- [2] Englert et al. (2007), **Konduktives Knochenersatzmaterial mit variabler Antibiotikaversetzung [Conductive bone substitute material with variable antibiotic delivery]**, Unfallchirurg. 110(5):408-413.
- [3] Standardized bulk volume, data on file at OSARTIS GmbH.
- [4] von Stechow and Rauschmann (2009), **Effectiveness of combination use of antibiotic-loaded PerOssal® with spinal surgery in patients with spondylodiscitis**, Eur Surg Res. 43(3):298-305.
- [5] Kraus und Schnettler (2008), **Gutachten bei Osteitis [Expert opinion in osteitis]**, in: Bericht über die Unfallmedizinische Tagung in Mainz am 8./9.11.2008, Deutsche Gesetzliche Unfallversicherung (Hrsg.), Heft 108, ISBN 3-88383-082-8.
- [6] Fleege et al. (2012), **Systemische und lokale Antibiotikatherapie bei konservativ und operativ behandelten Spondylodiszitiden [Systemic and local antibiotic therapy of conservative and operative treatment of spondylodiscitis]**, Orthopäde. 41(9):727-735.
- [7] Fleege et al. (2020), **Development and current use of local antibiotic carriers in spondylodiscitis: Pilot study on reduction of duration of systemic treatment**, Orthopäde. 49(8):714-723.
- [8] Fleege et al. (2017), **Antibiotikatherapie der pyogenen Spondylodiszitis bei Erwachsenen [Antibiotic therapy of pyogenic spondylodiscitis in adults]**, Die Wirbelsäule. 01(4):265.
- [9] Release kinetic data on file at OSARTIS GmbH.
- [10] Visani et al. (2018), **Treatment of chronic osteomyelitis with antibiotic-loaded bone void filler systems: an experience with hydroxyapatites calcium-sulfate biomaterials**, Acta Orthop Belg. 84(1):25-29.
- [11] Sakellariou et al. (2015), **Combination of Calcium Hydroxyapatite Antibiotic Carrier with Cement Spacers in Peri-Prosthetic Knee Infections**, Surg Infect. 16(6):748-54.
- [12] Jiménez-Martín et al. (2008), **Use of calcium sulfate and hydroxyapatite with antibiotics in osteomyelitis of the hand: Two clinical cases. Utilidad del sulfato cálcico e hidroxiapatita con antibióticos en las osteomielitis de la mano, a propósito de 2 casos clínicos**, Trauma Fund MAPFRE 20(1):45-48.

Note

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