

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.

PerOssal® Product Guide | Content

General Information

Package sizes & bulk volume	2
Fluid uptake & preparation time	3

Use of Antibiotics

Dosage recommendation* for antibiotic load based on antibiotic products available in the market	4
Examples dosage recommendation	5
Antibiotic solution (single application)	
Gentamicin 1x50	5
Gentamicin 1x6, 2x6	6
Antibiotic powder (single application)	
Vancomycin 1x50	7
Vancomycin 1x6, 2x6	8
Combined application	
Vancomycin & Rifampicin	9
Gentamicin & Rifampicin	11
References	13

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 $\triangleq 1.5 \text{ cm}^3$ bulk volume

03-01031



1.5 cm³
bulk volume
total

2x6 12 pellets $\triangleq 3.0 \text{ cm}^3$ bulk volume

03-01032



3.0 cm³
bulk volume
total

1x50 50 pellets $\triangleq 12.5 \text{ cm}^3$ bulk volume

03-0102



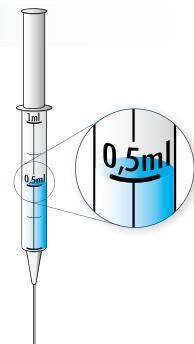
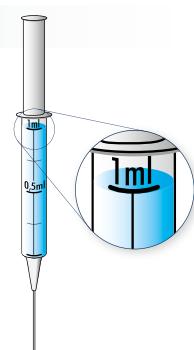
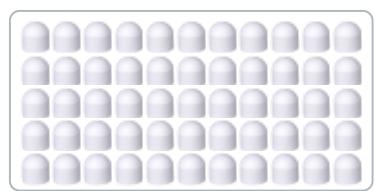
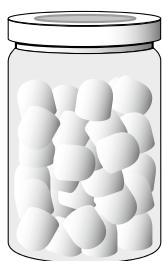
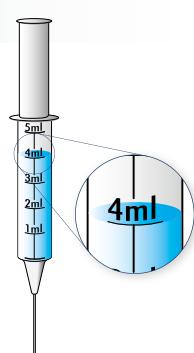
12.5 cm³
bulk volume
total

Note:

1 pellet $\triangleq 0.25 \text{ cm}^3$

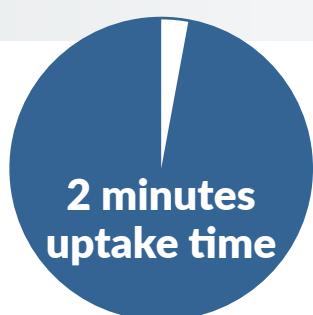
Fluid uptake

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:



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:



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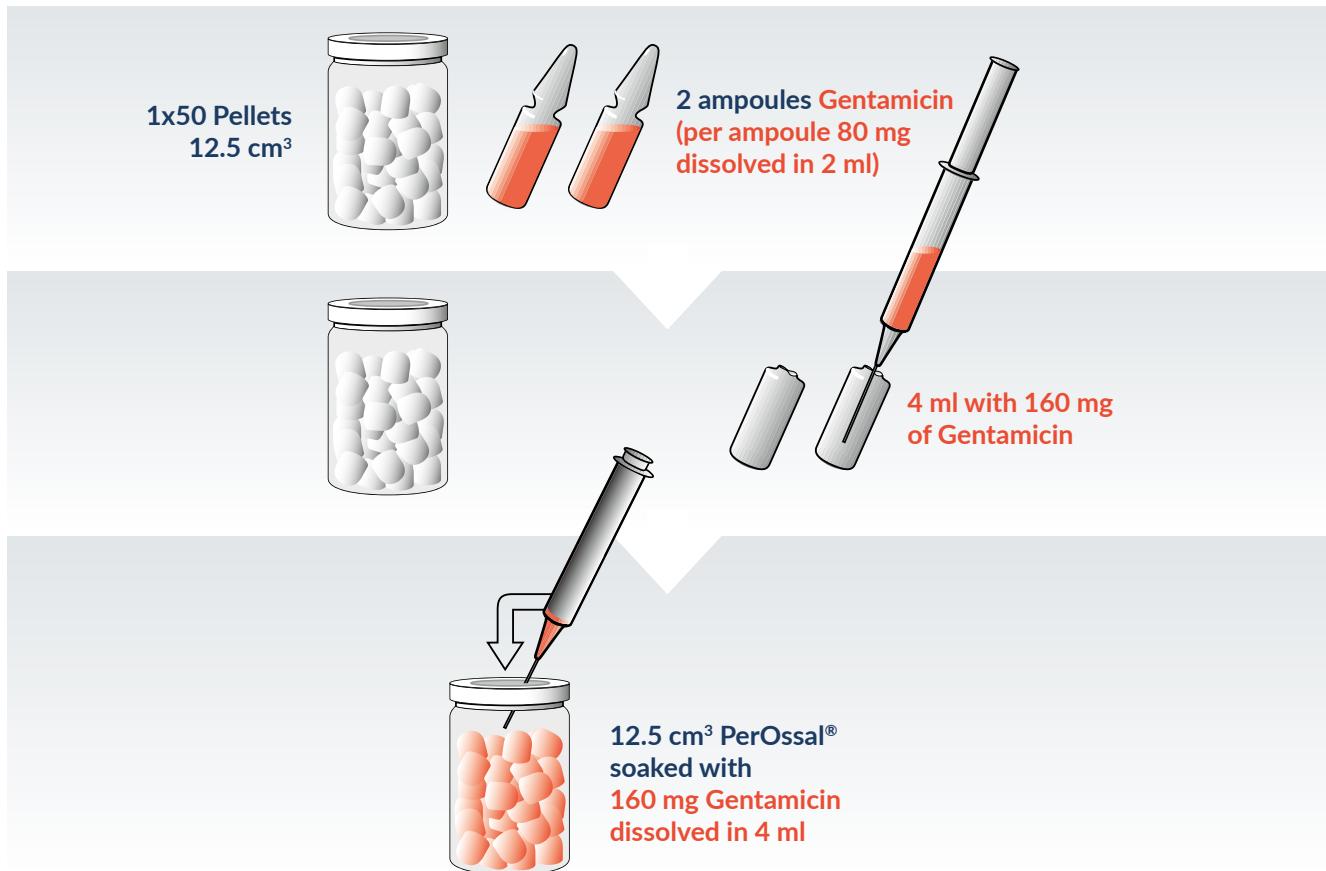
** e.g. sterile water for injection purposes (aqua ad injectabilia)



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

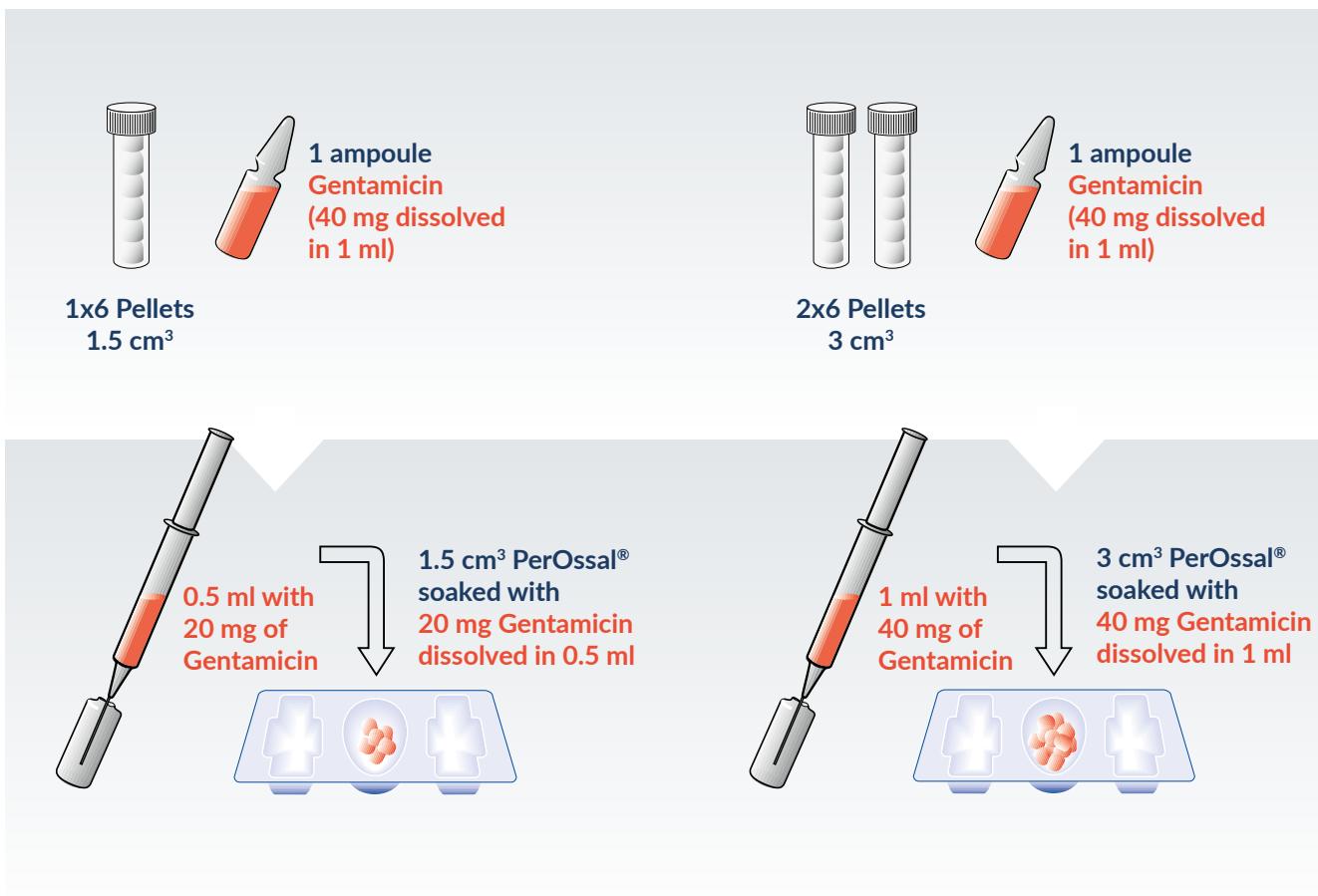
40
mg/ml



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

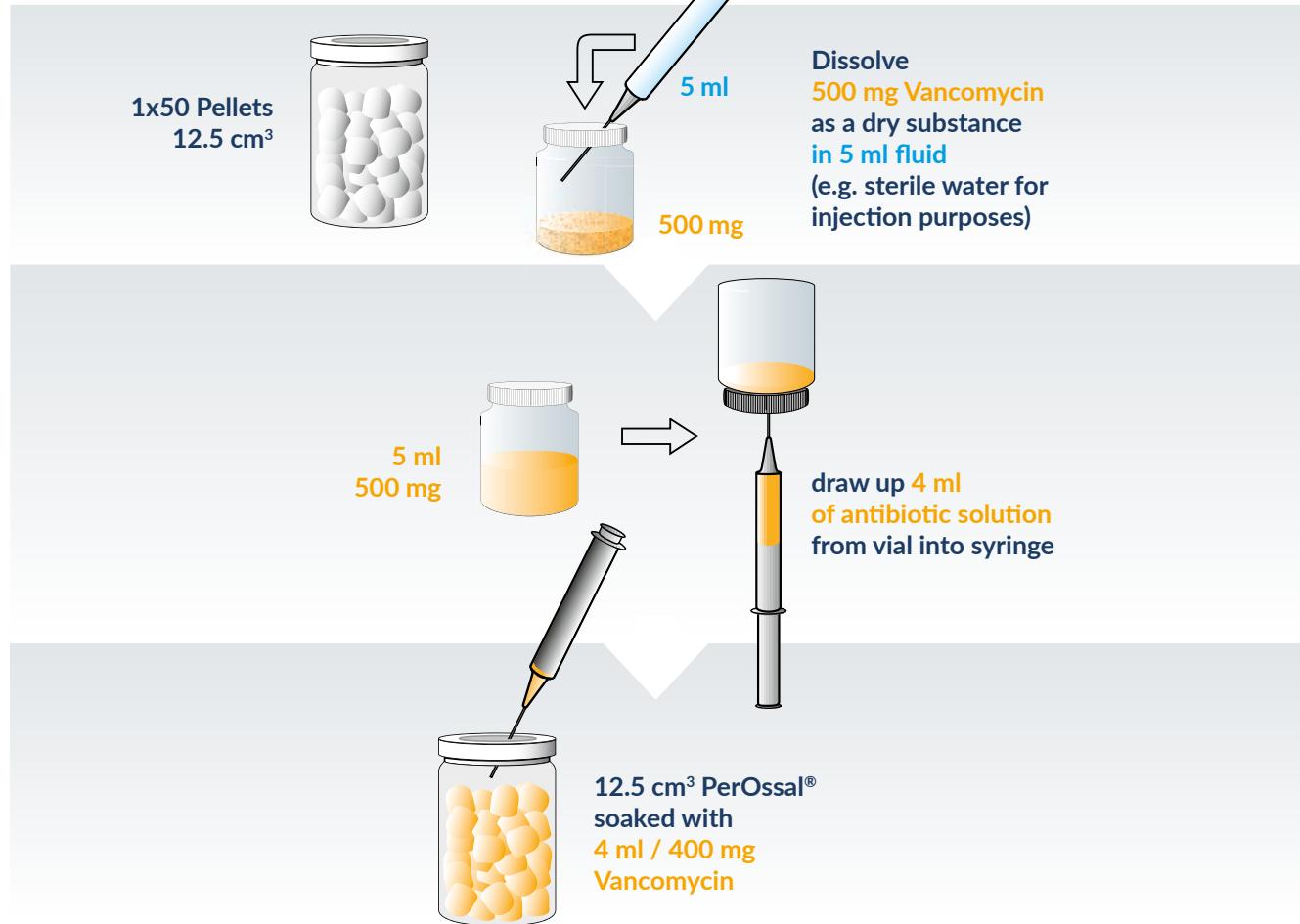
40
mg/ml



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

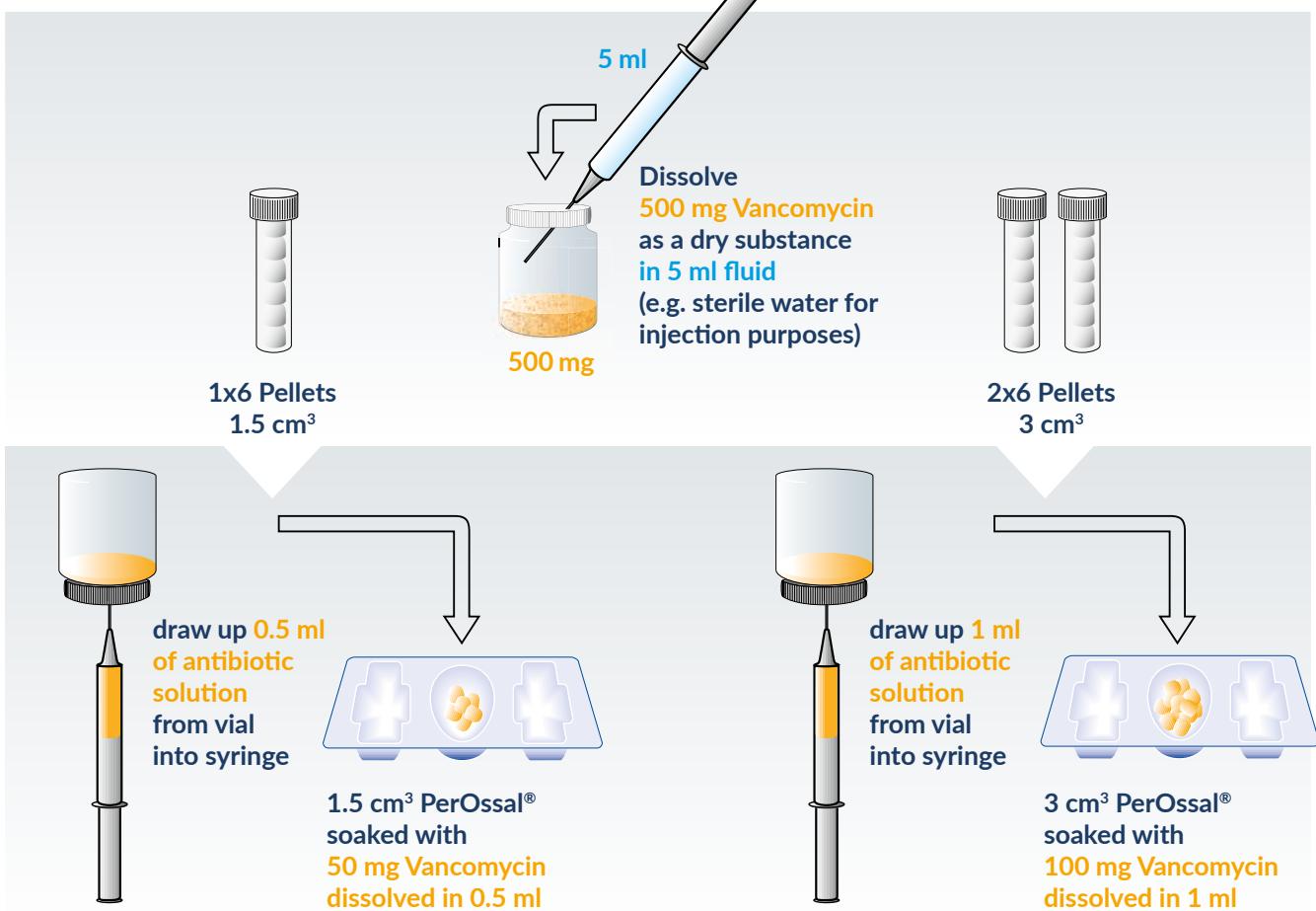
50 mg/ml



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

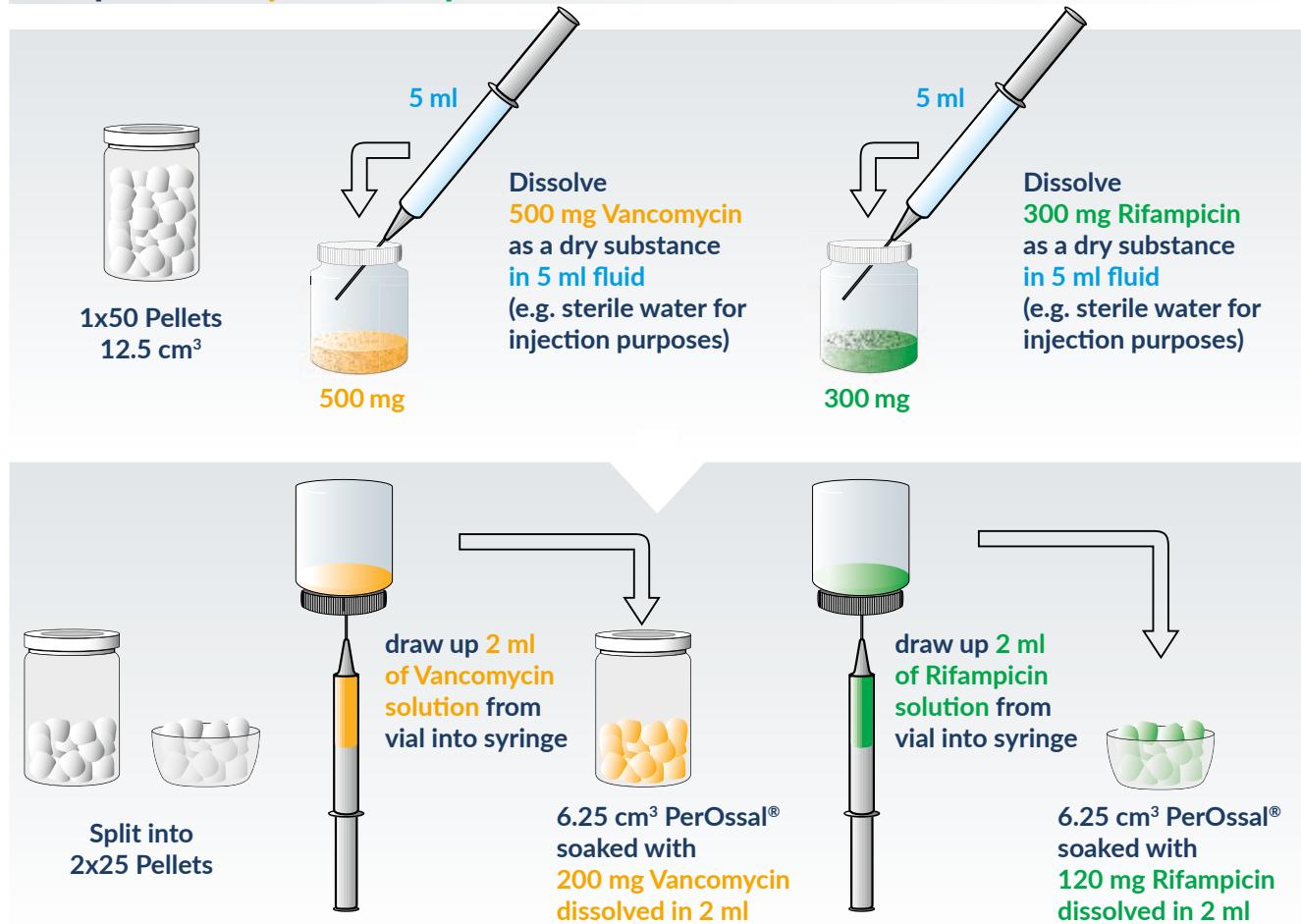
50
mg/ml



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

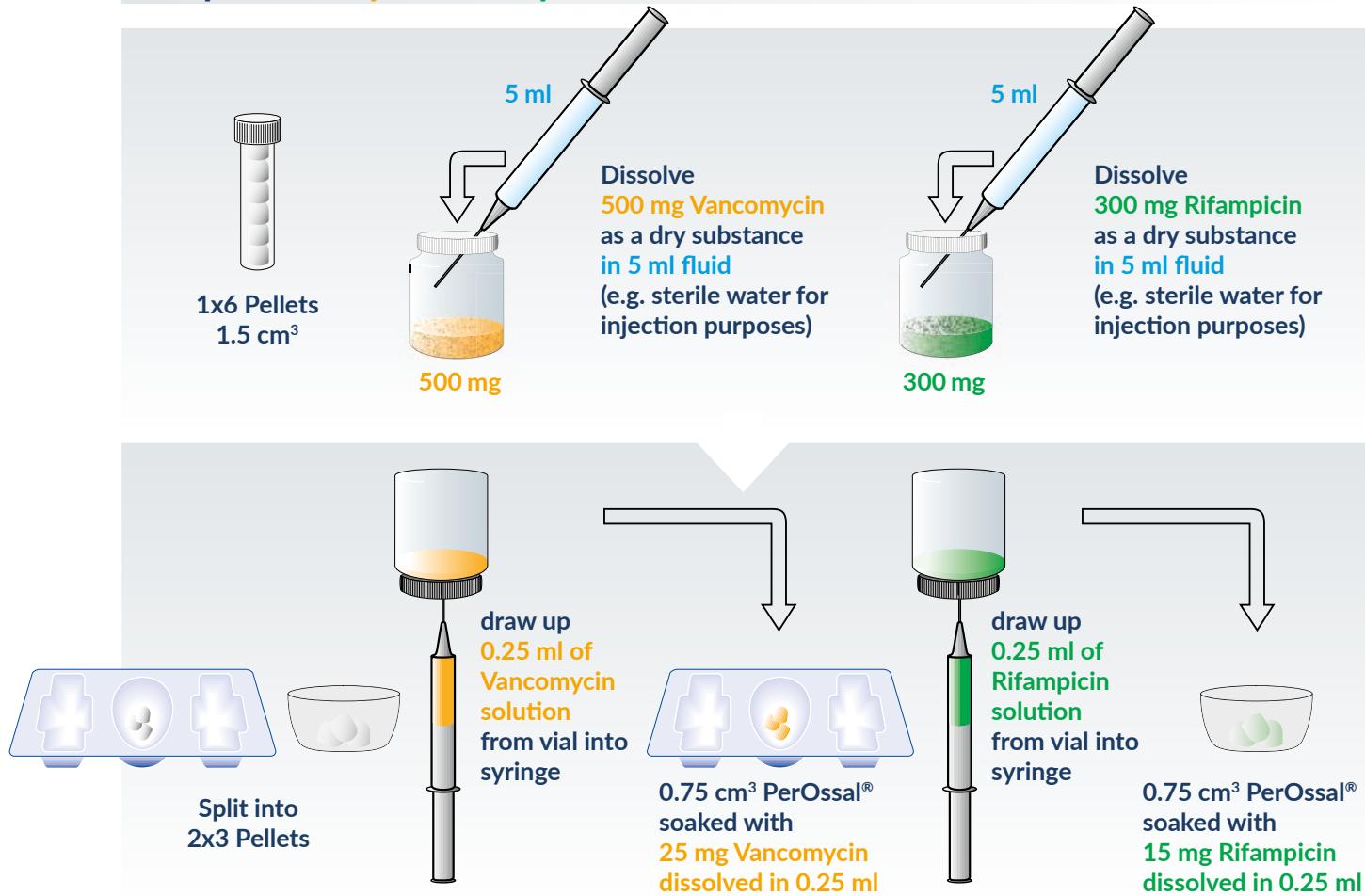
60 mg/ml



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

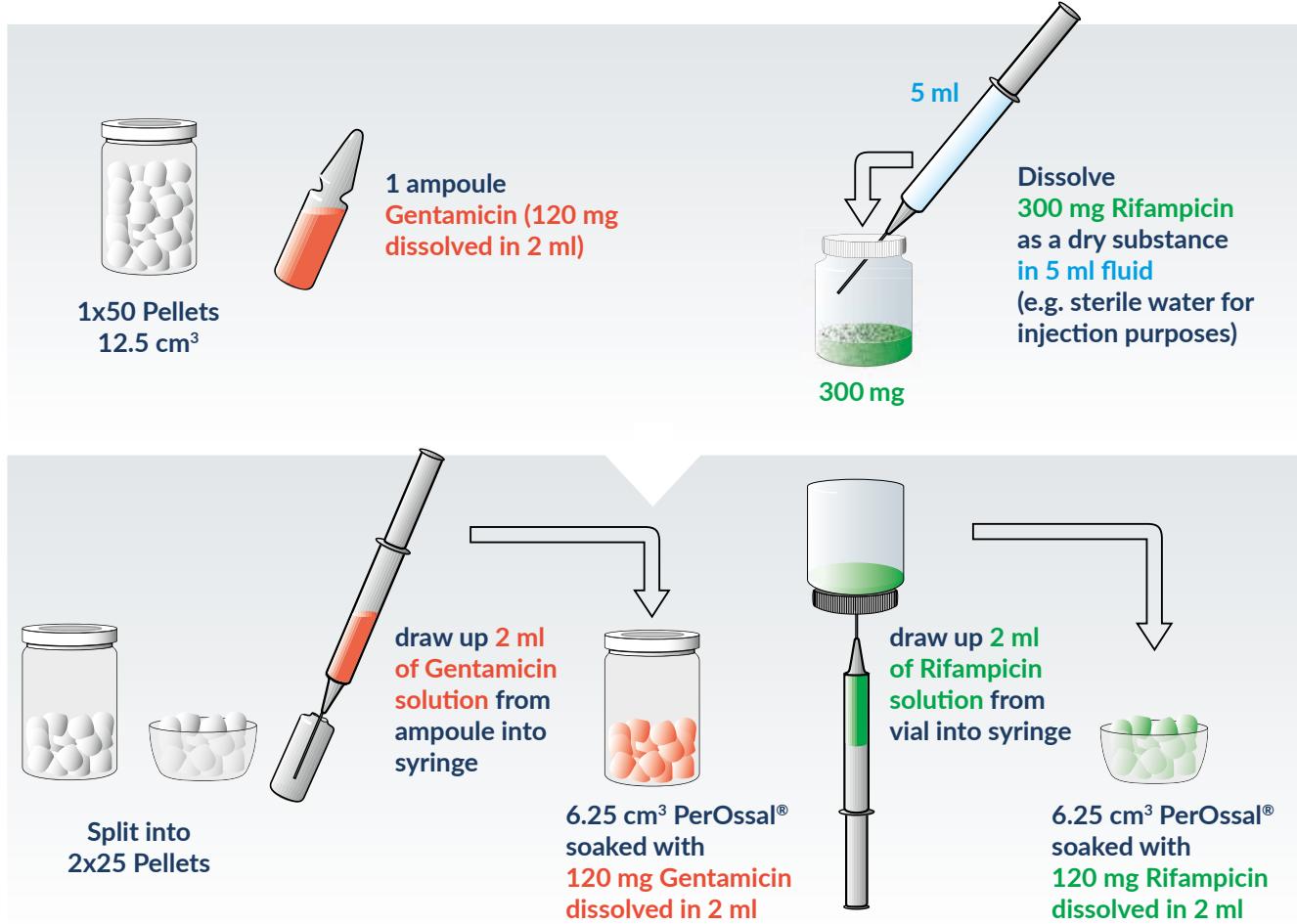
60 mg/ml



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

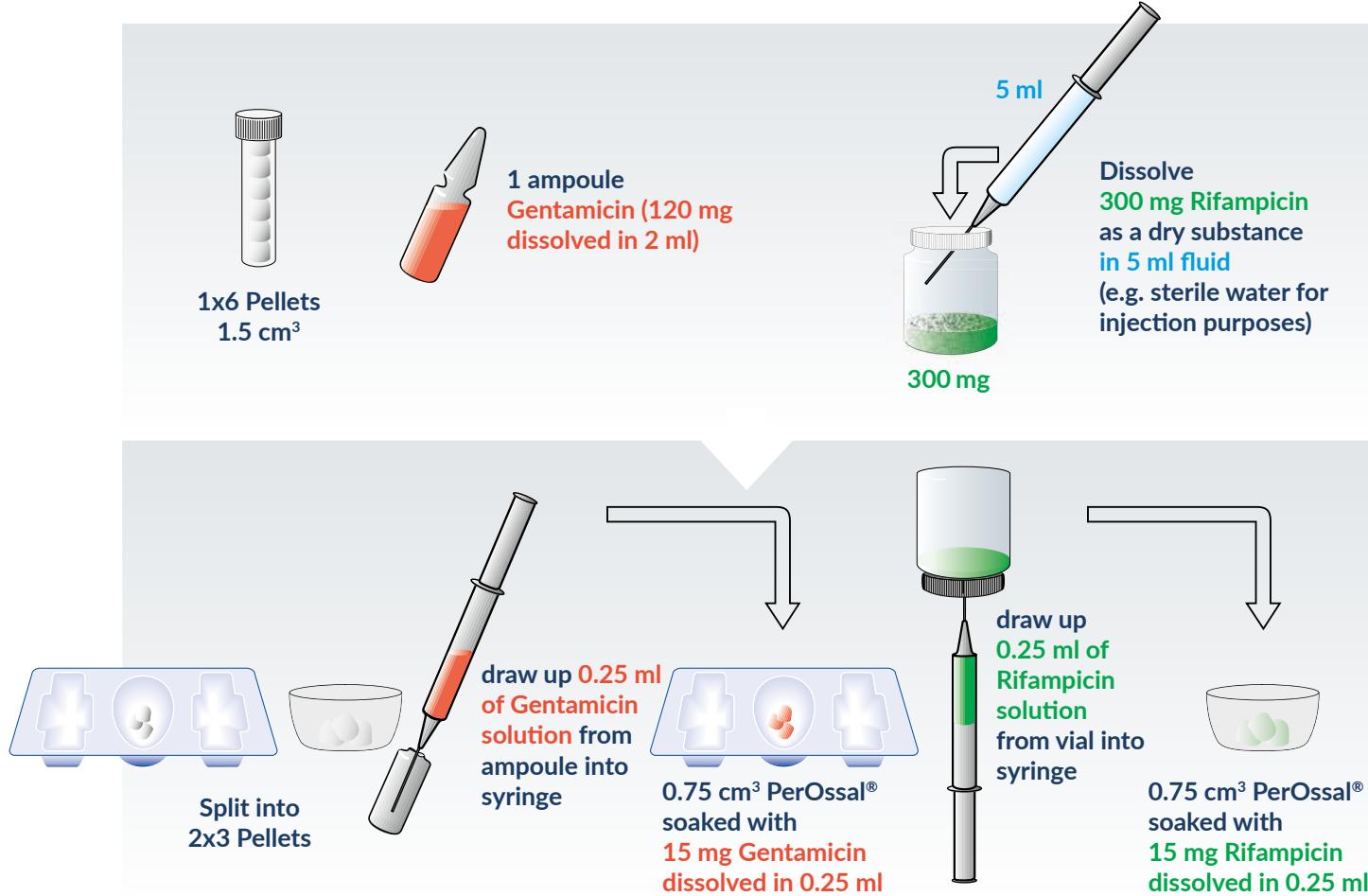
60 mg/ml



Antibiotic solution & powder (Combined application)

Dosage recommendation*

Example: Gentamicin & Rifampicin with PerOssal® 1x6



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

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