Table 14.1.4.1
Concomitant Medications
(Safety Analysis Set)

ATC Level I Drug Class/ Drug Name	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Any Concomitant Medication	15 (100.0%)	3 (23.1%)	6 (60.0%)	15 (100.0%)
ALIMENTARY TRACT AND METABOLISM	13 (86.7%)	2 (15.4%)	3 (30.0%)	14 (93.3%)
Loperamid	8 (53.3%)	0 (0.0%)	1 (10.0%)	9 (60.0%)
Pantoprazol	2 (13.3%)	0 (0.0%)	1 (10.0%)	3 (20.0%)
Buscopan	2 (13.3%)	0 (0.0%)	0 (0.0%)	2 (13.3%)
Lopedium	1 (6.7%)	1 (7.7%)	0 (0.0%)	2 (13.3%)
Omeprazol	2 (13.3%)	0 (0.0%)	0 (0.0%)	2 (13.3%)
Zofran	1 (6.7%)	0 (0.0%)	1 (10.0%)	2 (13.3%)
Imodium	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Loperamin	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Magnesium	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Multivitamin	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Saccharomyces boulardii	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (6.7%)
Simeticon	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Vigantoletten	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Zinc	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
ANTIINFECTIVES FOR SYSTEMIC USE	12 (80.0%)	1 (7.7%)	2 (20.0%)	14 (93.3%)
Viread	9 (60.0%)	1 (7.7%)	1 (10.0%)	11 (73.3%)

ATC = Anatomic Therapeutic Chemical.
Prior and Concomitant medications are coded using the World Health Organization (WHO) Drug Dictionary Version WHO2015SEP.
Medications that have a stop date prior to the first dose of study drug are considered as prior. Concomitant medications are defined as non-study medications with a stop date on or after the first dose of study drug, and a start date on or before the date of the patient's last visit in the study.

Table 14.1.4.1
Concomitant Medications
(Safety Analysis Set)

ATC Level I Drug Class/ Drug Name	50 mg/100 mg (N=15)	75 mg/100 mg (N=13)	100 mg/100 mg (N=10)	Overall (N=15)
Adefovir	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Amoxicillin	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (6.7%)
Baraclude	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Lamivudine	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
MUSCULO-SKELETAL SYSTEM	3 (20.0%)	1 (7.7%)	1 (10.0%)	5 (33.3%)
Ibuprofen	3 (20.0%)	1 (7.7%)	0 (0.0%)	4 (26.7%)
Foster	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Ibuflam	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (6.7%)
CARDIOVASCULAR SYSTEM	3 (20.0%)	0 (0.0%)	0 (0.0%)	3 (20.0%)
Carvedilol	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Lisinopril	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Nebivolol	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
NERVOUS SYSTEM	2 (13.3%)	0 (0.0%)	0 (0.0%)	2 (13.3%)
Levetiracetam	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Paracetamol	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
SENSORY ORGANS	1 (6.7%)	0 (0.0%)	1 (10.0%)	2 (13.3%)
Eye drops	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (6.7%)
Pilocarpine	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)

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Concomitant Medications
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Sodium hyaluronate	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
GENITO URINARY SYSTEM AND SEX HORMONES	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (6.7%)
Ethinylestradiol w/etonogestrel	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (6.7%)
RESPIRATORY SYSTEM	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
Fluticasone w/salmeterol	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
L-thyroxin	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)

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