

NORMATIVE INSTRUCTION – IN No. 360 OF 23 APRIL 2025

It defines the list of isolated or combined substances used in prescription and prescription-retaining medicinal products, as provided for in Collegiate Board Resolution – RDC No. 471 of 23 February 2021.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VII and Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Normative Instruction, as decided upon in a meeting held on 16 April 2025, and I, Acting Director-President, determine its publication.

Article 1. The list of substances classified as antimicrobials for prescription use, isolated or in combination, as referred to in Collegiate Board Resolution – RDC No. 471 of 23 February 2021, published in the Federal Official Gazette No. 36 of 24 February 2021, Section 1, Page 85, is hereby defined:

- 1 – clavulanic acid;
- 2 – fusidic acid;
- 3 – nalidixic acid;
- 4 – oxolinic acid;
- 5 – piperimidic acid;
- 6 – amikacin;
- 7 – amoxicillin;
- 8 – ampicillin;
- 9 – cefuroxime axetil;
- 10 – azithromycin;
- 11 – aztreonam;
- 12 – bacitracin;
- 13 – besifloxacin;
- 14 – brodimoprim;
- 15 – capreomycin;
- 16 – carbenicillin;

- 17 – cefaclor;
- 18 – cefadroxil;
- 19 – cephalexin;
- 20 – cephalothin;
- 21 – cefazolin;
- 22 – cefepime;
- 23 – cefodizime;
- 24 – cefoperazone;
- 25 – cefotaxime;
- 26 – cefoxitin;
- 27 – cefpodoxime;
- 28 – cefpirome;
- 29 – cefprozil;
- 30 – ceftadizime;
- 31 – ceftaroline fosamil;
- 32 – ceftobiprole;
- 33 – ceftriaxone;
- 34 – cefuroxime;
- 35 – ciprofloxacin;
- 36 – clarithromycin;
- 37 – clindamycin;
- 38 – clofazimine;
- 39 – chlorphenesin;
- 40 – chloramphenicol;
- 41 – cloxacillin;
- 43 – dactinomycin;
- 44 – daptomycin;
- 45 – dapsone;
- 46 – delamanid;
- 47 – dicloxacillin;
- 48 – diphenyl sulfone;

49 – dihydrostreptomycin;
50 – dirithromycin;
51 – doripenem;
52 – doxycycline;
53 – erythromycin;
54 – ertapenem;
55 – spectinomycin;
56 – spiramycin;
57 – streptomycin;
58 – ethambutol;
59 – ethionamide;
60 – fosfomicin;
61 – phthalylsulfathiazole;
62 – gatifloxacin;
63 – gemifloxacin;
64 – gentamicin;
65 – gramicidin;
66 – imipenem;
67 – isoniazid;
68 – levofloxacin;
69 – linezolid;
70 – lymecycline;
71 – lincomycin;
72 – lomefloxacin;
73 – loracarbef;
74 – mandelamine;
75 – meropenem;
76 – metampicillin;
77 – metronidazole;
78 – minocycline;
79 – myocamicin;

80 – mitomycin;
81 – moxifloxacin;
82 – mupirocin;
83 – neomycin;
84 – netilmicin;
85 – nitrofurazone;
86 – nitrofurantoin;
87 – nitroxoline;
88 – norfloxacin;
89 – ofloxacin;
90 – oxacillin;
91 – oxytetracycline;
92 – pefloxacin;
93 – penicillin G;
94 – penicillin V;
95 – piperacillin;
96 – pyrazinamide;
97 – polymyxin B;
98 – pristinamycin;
99 – protionamide;
100 – retapamulin;
101 – rifabutin;
102 – rifamycin;
103 – rifampicin;
104 – rifapentine;
105 – rosoxacin;
106 – roxithromycin;
107 – sulbactam;
108 – sulfacetamide;
109 – sulfadiazine;
110 – sulfadoxine;

- 111 – sulfaguanidine;
- 112 – sulfamerazine;
- 113 – sulfanilamide;
- 114 – sulfamethizole;
- 115 – sulfamethoxazole;
- 116 – sulfamethoxy pyridazine;
- 117 – sulfamethoxy pyrimidine;
- 118 – sulfathiazole;
- 119 – sultamicillin;
- 120 – tazobactam;
- 121 – tedizolid;
- 122 – teicoplanin;
- 123 – telithromycin;
- 124 – tetracycline;
- 125 – thiamphenicol;
- 126 – ticarcillin;
- 127 – tigecycline;
- 128 – thyrothricin;
- 129 – tobramycin;
- 130 – trimethoprim;
- 131 – trovafloxacin; and
- 132 – vancomycin.

Paragraph 1. This list does not apply to antimicrobials for exclusive hospital use.

Paragraph 2. Prescriptions for medicinal products containing the substances mentioned in the caption of this article are valid for 10 (ten) days from the date of issue.

Article 2. The list of substances classified as glucagon-like peptide-1 (GLP-1) receptor agonists, for prescription use, alone or in combination, provided for in Collegiate Board Resolution – RDC No. 471 of 23 February 2021, is hereby defined.

- 1 – semaglutide;
- 2 – liraglutide;
- 3 – dulaglutide;
- 4 – tirzepatide; and

5 – lixisenatide.

Paragraph 1. The prescription of medicinal products based on the substances mentioned in the caption of this article is valid for 90 (ninety) days, counting from the date of issue.

Paragraph 2. Within 180 (one hundred and eighty) days after the date of publication of this Normative Instruction, the manufacture of new batches of the medicinal products referred to in the caption of this article is permitted, with the packaging marked with a red stripe, without the words "SALE UNDER MEDICAL PRESCRIPTION – MAY ONLY BE SOLD WITH RETENTION OF THE PRESCRIPTION", as well as the package insert model. Dispensing is permitted until the end of its validity period, upon presentation and retention of the prescription, in accordance with Collegiate Board Resolution – RDC No. 471 of 2021.

Article 3. Normative Instruction – IN No. 244 of 21 August 2023, published in the Federal Official Gazette No. 161 of 23 August 2023, Section 1, page 80, is hereby revoked.

Article 4. This Normative Instruction shall come into effect 60 (sixty) days after the date of its publication.

Rômison Rodrigues Mota

Acting Director-President