

Prescribing Information
Co-trimoxazole Tablets BP
BALTRIM FORTE

Each uncoated tablet contains:
 Sulfamethoxazole BP 800 mg,
 Trimethoprim BP 160 mg

COMPOSITION:

CLINICAL PHARMACOLOGY
BALTRIM FORTE is rapidly absorbed following oral administration. Both sulfamethoxazole and trimethoprim exist in the blood as unbound, protein-bound, and metabolized forms. Sulfamethoxazole also exists as the conjugated form. The elimination half-life of sulfamethoxazole is approximately 10 hours. The elimination half-life of trimethoprim has been identified. The principal metabolites of trimethoprim are the 1- and 4-hydroxy derivatives. Sulfamethoxazole and trimethoprim are excreted in the urine. Approximately 44% of trimethoprim and 70% of sulfamethoxazole are bound to plasma proteins. The presence of 10 mg percent sulfamethoxazole in plasma decreases the protein binding of trimethoprim by an insignificant degree.

Peak blood levels for the individual components occur 1 to 4 hours after oral administration. The mean serum half-lives of sulfamethoxazole and trimethoprim are 10 and 8 to 10 hours, respectively. However, patients with severely impaired renal function may require a longer interval between doses. The elimination half-life of trimethoprim is approximately 11 hours. Detectable amounts of trimethoprim and sulfamethoxazole are present in the blood 24 hours after drug administration. During administration of 160 mg trimethoprim and 800 mg sulfamethoxazole b.i.d., the mean steady-state plasma concentrations of trimethoprim and sulfamethoxazole were 2.7 mg/mL and 66.0 mg/mL, respectively. These steady-state levels were achieved after 3 days of drug administration. Sulfamethoxazole and trimethoprim is primarily excreted in the urine through both glomerular filtration and tubular secretion. Urine concentrations of both sulfamethoxazole and trimethoprim are consistently higher than the concentrations in the blood. The average percentage of the dose excreted in urine from 0 to 72 hours after a single oral dose of 160 mg trimethoprim and 800 mg sulfamethoxazole was 78.5% and 80.5%, respectively. Sulfamethoxazole, as free sulfamethoxazole, with its remaining N-acetylated metabolite. When administered together as BALTRIM FORTE, neither sulfamethoxazole nor trimethoprim affects the urinary excretion of the other. Sulfamethoprim also distributes to bronchial secretions, and both pass the placental barrier and are excreted in human milk.

INDICATIONS AND USAGE

Urinary Tract Infections
 Sulfamethoxazole and trimethoprim are effective against most urinary tract infections. Escherichia coli, Klebsiella species, Enterobacter species, Morganella morganii, Proteus mirabilis, and Proteus vulgaris. It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective 960 mg dose of BALTRIM FORTE.

Use in Children

For the treatment of acute otitis media in pediatric patients due to susceptible strains of Streptococcus pneumoniae or Hemophilus influenzae when, in the judgment of the physician, BALTRIM FORTE offers some advantage over the use of other antimicrobial agents. For the treatment of acute otitis media in pediatric patients due to susceptible strains of Streptococcus pneumoniae or Hemophilus influenzae when, in the judgment of the physician, BALTRIM FORTE offers some advantage over the use of other antimicrobial agents. For the treatment of acute otitis media in pediatric patients under two years of age. BALTRIM FORTE is not indicated for prophylactic or prolonged administration in otitis media at any age.

Acute Exacerbations of Chronic Bronchitis in Adults

BALTRIM FORTE is indicated for the treatment of acute exacerbations of chronic bronchitis due to susceptible strains of Streptococcus pneumoniae or Hemophilus influenzae when, in the judgment of the physician, BALTRIM FORTE offers some advantage over the use of a single antimicrobial agent.

Treatment of Pneumocystis carinii pneumonia

BALTRIM FORTE is indicated for the treatment of Pneumocystis carinii pneumonia due to susceptible strains of the organism in patients with acquired immunodeficiency syndrome (AIDS) who are immunosuppressed and considered to be at an increased risk of developing Pneumocystis carinii pneumonia.

DOSEAGE AND ADMINISTRATION
 Contained in pediatric patients less than 2 months of age.
 For the treatment of urinary tract infections, two BALTRIM FORTE tablets, an identical daily dosage is used for 5 days in the treatment of otitis media.

Pediatric Patients: The recommended dose for pediatric patients with urinary tract infections or acute otitis media is 8 mg/kg of trimethoprim and 16 mg/kg of sulfamethoxazole, administered as two divided doses every 12 hours for 10 days in children 2 months of age and older, and for 5 days in the treatment of otitis media.

Acute Exacerbations of Chronic Bronchitis in Adults: The usual adult dosage in the treatment of acute exacerbations of chronic bronchitis is two BALTRIM FORTE tablets every 12 hours for 12 hours. In the treatment of acute exacerbations of chronic bronchitis in two BALTRIM FORTE tablets, the usual adult dosage is two BALTRIM FORTE tablets every 12 hours for 5 days.

SIDE EFFECTS

The most common adverse effects are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (rash, urticaria, erythema multiforme, exfoliative dermatitis, and toxic epidermal necrolysis). Other adverse effects include Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia, other blood dyscrasias, and hypersensitivity of the respiratory tract.

DRUG INTERACTIONS

In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported.

When BALTRIM FORTE is administered with theophylline, theophylline levels are increased. Patients who are receiving theophylline therapy, and theophylline level should be monitored. BALTRIM FORTE may inhibit the hepatic metabolism of theophylline, resulting in increased plasma levels of theophylline. Theophylline clearance rate by 39% and decreased theophylline metabolic clearance rate by 27%. When administering these drugs concurrently, the theophylline dose should be reduced by 25% to 50%.

Some drugs also displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

WARNINGS

SULFONAMIDES, INCLUDING SULFONAMIDE-CONTAINING PRODUCTS SUCH AS TRIMETHOPRIM AND SULFAMETHOXAZOLE, MAY CAUSE SEVERE AND LIFE-THREATENING ADVERSE REACTIONS. A SIGN OF ADVERSE REACTION IS RASH. ADVERSE REACTIONS TO RASH SHOULD BE FOLLOWED BY A MORE SEVERE REACTION, SUCH AS STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, HEPATIC NECROSIS, AND SERIOUS BLOOD DISORDER.

PRECAUTIONS

BALTRIM FORTE should be given with caution to patients with impaired renal or hepatic function. In those with possible renal deficiency (e.g., the elderly, chronic alcoholics, patients receiving anticonvulsant therapy, patients with severe hepatic dysfunction, patients receiving diuretics, patients receiving theophylline therapy, patients receiving glucose-6-phosphate dehydrogenase-deficient individuals, hemolytic may occur. This reaction is frequently dose-related.

Storage: Store in a cool place.

TM-Trade Mark

Manufactured by:

BAL PHARMA LIMITED
 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.

UI - 1146/A

Front

Back

1.	Product Name	Baltrim Forte (Sun Rwanda)
2.	Code Number	Lit-1146/A
3.	Dimension	100 X 135 mm
4.	No. of Colours	1
5.	Colours	Black
6.	GSM and Board	70 GSM, Maplitho Paper
7.	Embossing	No
8.	Folding	1 fold along with length and 1 fold along with width
Revision History		
Sl. No.	Reason for Revision	Code No.
1.	New Artwork	Lit-1146/A
File Name		Lit-5 (15)
Prepared By:		Checked By:
Graphic Designer		Q.C. Officer
Date:		Date:
Approved By:		Q.A. Head