

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE- ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated
Meijer Distribution, Inc

Drug Facts

ACTIVE INGREDIENTS (IN EACH CAPLET)

Ibuprofen, USP 200 mg (NSAID)*

Pseudoephedrine HCl, USP 30 mg

*nonsteroidal anti-inflammatory drug

PURPOSES

Pain reliever/Fever reducer

Nasal decongestant

USES

Temporarily relieves these symptoms associated with the common cold or flu:

- fever
- sinus pressure
- nasal congestion
- headache
- minor body aches and pains

WARNINGS

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- in children under 12 years of age
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, thyroid disease, diabetes or have trouble urinating due to an enlarged prostate gland
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains pseudoephedrine or any other nasal decongestant
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
- symptoms continue or get worse
- any new symptoms appear
- you get nervous, dizzy, or sleepless
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- redness or swelling is present in the painful area

If pregnant or breast-feeding

Ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

DIRECTIONS

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years of age and over:
 - take 1 caplet every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 caplet, 2 caplets may be used.
 - do not use more than 6 caplets in any 24-hour period unless directed by a doctor
- children under 12 years of age: do not use

OTHER INFORMATION

- store at 20 - 25° C (68 - 77° F). Avoid excessive heat above 40° C (104° F).
- read all warnings and directions before use. Keep carton.
- **TAMPER EVIDENT: DO NOT USE IF BLISTER UNITS ARE TORN, BROKEN OR SHOW ANY SIGNS OF TAMPERING.**

INACTIVE INGREDIENTS

Acacia, calcium carbonate, carnauba wax, confectioner's sugar, corn starch, croscarmellose sodium, crospovidone, FD&C Blue no. 2 Aluminum Lake, FD&C Red no. 40 Aluminum Lake, FD&C Yellow no. 6 Aluminum Lake, gelatin, guar gum, hydrogenated vegetable oil, hydroxypropyl cellulose, iron oxide black, kaolin, polyethylene glycol, powdered cellulose, povidone, pregelatinized starch, propylene glycol, shellac, silicon dioxide, sodium benzoate, sucrose, talc, titanium dioxide, white wax

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

NDC 41250-423-40

Compare to Advil® Cold & Sinus active ingredients**

meijer™

Non-Drowsy

Cold & Sinus Relief

Ibuprofen and Pseudoephedrine HCl Tablets, USP

IBUPROFEN, USP 200 mg · PAIN RELIEVER/FEVER REDUCER (NSAID)*

PSEUDOEPHEDRINE HCl, USP 30 mg · NASAL DECONGESTANT

Relieves Sinus Pressure, Nasal Congestion and Fever

40 Coated Caplets†

†oval-shaped tablets

***nonsteroidal anti-inflammatory drug**

DIST. BY MEIJER

5089123/R0811

1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25
 26
 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

Drug Facts (continued)

When taking this medicine:
• Be sure to avoid alcohol, milk, or other drinks that may interfere with the medicine's action.
• Do not take this medicine with other medicines without your doctor's approval.
• Do not take this medicine with grapefruit or grapefruit juice, as this may increase the risk of side effects.
• Do not take this medicine with other medicines that may cause drowsiness, such as alcohol, sedatives, or tranquilizers.
• Do not take this medicine with other medicines that may cause dizziness, such as antihistamines or pain relievers.
• Do not take this medicine with other medicines that may cause constipation, such as iron supplements or laxatives.
• Do not take this medicine with other medicines that may cause dry mouth, such as anticholinergics or decongestants.
• Do not take this medicine with other medicines that may cause blurred vision, such as anticholinergics or eye drops.
• Do not take this medicine with other medicines that may cause difficulty swallowing, such as anticholinergics or throat lozenges.
• Do not take this medicine with other medicines that may cause skin irritation, such as topical creams or ointments.
• Do not take this medicine with other medicines that may cause allergic reactions, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause liver or kidney problems, such as acetaminophen or NSAIDs.
• Do not take this medicine with other medicines that may cause low blood pressure, such as blood pressure medications or diuretics.
• Do not take this medicine with other medicines that may cause high blood pressure, such as stimulants or decongestants.
• Do not take this medicine with other medicines that may cause heart problems, such as beta-blockers or calcium channel blockers.
• Do not take this medicine with other medicines that may cause breathing problems, such as inhalers or decongestants.
• Do not take this medicine with other medicines that may cause seizures, such as antiepileptics or stimulants.
• Do not take this medicine with other medicines that may cause mental health problems, such as antidepressants or antipsychotics.
• Do not take this medicine with other medicines that may cause bleeding, such as blood thinners or aspirin.
• Do not take this medicine with other medicines that may cause low blood sugar, such as insulin or oral diabetes medications.
• Do not take this medicine with other medicines that may cause high blood sugar, such as corticosteroids or diuretics.
• Do not take this medicine with other medicines that may cause electrolyte imbalances, such as diuretics or laxatives.
• Do not take this medicine with other medicines that may cause dehydration, such as diuretics or laxatives.
• Do not take this medicine with other medicines that may cause kidney stones, such as calcium supplements or vitamin D.
• Do not take this medicine with other medicines that may cause urinary tract infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause vaginal infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause yeast infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause skin infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause eye infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause ear infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause sinus infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause respiratory infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause urinary tract infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause vaginal infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause yeast infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause skin infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause eye infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause ear infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause sinus infections, such as antibiotics or antifungals.
• Do not take this medicine with other medicines that may cause respiratory infections, such as antibiotics or antifungals.

1-800-4-A-MEIJER
Compare to Advil® Cold & Sinus
active ingredients

meijer™

Non-Drowsy

Cold & Sinus Relief

Ibuprofen and Pseudoephedrine HCl Tablets, USP

IBUPROFEN, USP 200 mg • PAIN RELIEVER/FEVER REDUCER (NSAID)*
PSEUDOEPHEDRINE HCl, USP 30 mg • NASAL DECONGESTANT

Relieves Sinus Pressure,
Nasal Congestion and Fever

40 Coated Caplets* lozenge-shaped tablets

*nonsteroidal anti-inflammatory drug

This product is not manufactured or distributed by Wyeth Consumer Healthcare. Advil® is a registered trademark of Wyeth LLC.

7 19283 41952 1

 **meijer**

DIST. BY MEIJER
DISTRIBUTION, INC.,
2029 WALKER AVE NW
GRAND RAPIDS, MI 49644
www.meijer.com

Batch No. _____

Expiration Date: _____

Non Varnish Area

[illegible]

ibuprofen and pseudoephedrine hydrochloride tablet, sugar coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-423
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)		IBUPROFEN	200 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)		PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg
Inactive Ingredients			
Ingredient Name			Strength
ACACIA (UNII: 5C5403N26O)			
CALCIUM CARBONATE (UNII: H0G9379FGK)			
CARNAUBA WAX (UNII: R12CBM0EIZ)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CROSPOVIDONE (UNII: 68401960MK)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GUAR GUM (UNII: E89I1637KE)			
TRISTEARIN (UNII: P6OCJ2551R)			
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)			
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			
KAOLIN (UNII: 24H4NWX5CO)			
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
POWDERED CELLULOSE (UNII: SMD1X3XO9M)			
POVIDONE (UNII: FZ989GH94E)			
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SHELLAC (UNII: 46N107B71O)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SUCROSE (UNII: C151H8M554)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WHITE WAX (UNII: 7G1J5DA97F)			
Product Characteristics			
Color	brown	Score	no score
Shape	OVAL (Caplets)	Size	14mm
Flavor		Imprint Code	423
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-423-40	40 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074567	10/13/2001	

Labeler - Meijer Distribution, Inc (006959555)**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(41250-423)

Revised: 12/2012

Meijer Distribution, Inc