



Billing and Reimbursement Guide

- Codes and guidance on completing claim forms for Medicare Fee-for-Service, Medicare Advantage, and commercial payers
- Billing and reimbursement information for OMIDRIA
- Details on ordering OMIDRIA
- Helpful resources

About OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3%

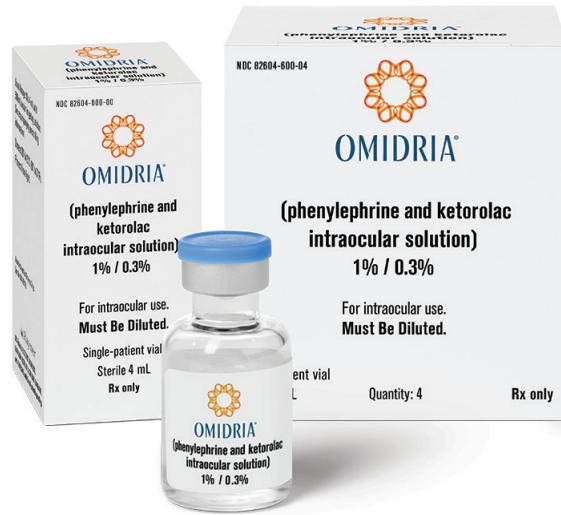
OMIDRIA is the first and only FDA-approved drug that provides continuous intracameral delivery of an NSAID and a mydriatic agent during cataract surgery.¹

OMIDRIA is a non-opioid medication added to the irrigating solution used during cataract surgery and lens replacement¹

Provides direct and continuous intracameral delivery of an NSAID and a mydriatic agent, delivered at the site of care.¹

Optimize time. Maximize control. Go dropless with OMIDRIA.

- Streamlines cataract surgery
- Effectively maintains pupil dilation and requires less use of PEDs¹⁻⁸
- Reduces complications such as IFIS, CME, and breakthrough iritis⁷
- Improved patient experience with less pain, greater visual acuity, and fewer to no drops^{1,2,9,10}
- Places control and surgical outcomes in surgeon's hands
- Minimizes the risks and liabilities of compounded products



CME=Cystoid Macular Edema; IFIS=Intraoperative Floppy Iris Syndrome;
NSAID=Nonsteroidal Anti-inflammatory Drug; PED=Pupil Expansion Device.

2 Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com


OMIDRIA®
(phenylephrine and ketorolac
intraocular solution)
1% / 0.3%

Coding for OMIDRIA*

OMIDRIA has a unique permanent J-code†

J1097¹¹

phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL

1 billing unit = 1 mL; one standard 4-mL vial = 4 units.

Sample CPT® codes ¹³	CPT modifier ¹²
66984 Uncomplicated cataract surgery	RT/LT
66982‡ Complex cataract surgery	Right eye/Left eye
66983, 66989, 66991, 66988 Related intraocular lens procedures	

HCPCS and NDC codes for OMIDRIA

HCPCS code ¹¹	APC	HCPCS modifier ^{14, 15}	Long descriptor ¹¹	NDC number ^{1, 20}
J1097	9324	JZ** TB***	Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL	82604-0600-04 (11-digit)

Important reminders

- The OMIDRIAssure program provides assistance for financially eligible uninsured or underinsured patients and those with insufficient commercial insurance†
- Questions related to a patient's eligibility for OMIDRIAssure should be addressed by calling the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), contacting your OMIDRIA Field Reimbursement Manager, or working directly with your payer provider representative
- Coverage and payment may vary by payer, contractual agreements, and site of service

INDICATIONS AND USAGE

OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

IMPORTANT SAFETY INFORMATION

The most commonly reported adverse reactions at $\geq 2\%$ are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

You are encouraged to report Suspected Adverse Reactions to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

CPT is a registered trademark of the American Medical Association.

*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of OMIDRIA in eligible patients. Rayner does not guarantee reimbursement. OMIDRIAssure program services are subject to change without notice.

‡If surgery is for complex cataract surgery, physician should note the ICD-10-CM code or reason why the surgery is complex.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code, APC=Ambulatory Payment Classification.

** Used in ASC and HOPD

*** Used in 340b Hospitals

Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com



OMIDRIA®

(phenylephrine and ketorolac
intraocular solution)
1% / 0.3%

Sample CMS-1500 Paper Claim Form¹⁶

Information contained herein is provided as a reference for obtaining reimbursement. This content is for informational purposes only. Rayner does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. Contact 1-877-OIMDRIA (1-877-664-3742) for more information about how to submit for OMIDRIA reimbursement.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification;
NDC=National Drug Code; NPI=National Provider Identifier.

**Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com**

Sample UB-04 (CMS-1450) Paper Claim Form¹⁷

Form Locator 4:

Enter 4-digit code _____
that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 013. The final digit is usually a "1," meaning one claim for the event

Enter all applicable patient information

Form Locator 17: Enter Patient Status

Form Locator 47:

Enter charges
for OMIDRIA

Form Locator 42*: Enter Revenue Code

Form Locator 43:

Enter N4 qualifier
and 11-digit NDC
number and UN1

Form Locator 44:
Enter unique Billing Code
for OMIDRIA and modifier
(JZ) *Note 340b add
TR modifier.

Form Locator 44:

Form Locator 46:

Form Locator 50A:
If Medicare is the
primary payer, enter
"Medicare" on line A

Form Locator 67:

Form Locator 66:

Form Locator 80:
Used to display remarks
or additional information
that may be needed to
process a claim

1 Any Hospital 123 Any Street Philadelphia, PA 19103		2 Any Hospital 123 Any Street Philadelphia, PA 19103		3a PAT- CNTL # 1234 b. MED- REC. # 98765	4 TYPE OF BILL O131
8 PATIENT NAME b Doe, John		9 PATIENT ADDRESS b Philadelphia		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM 7/1/2013 THROUGH 7/31/2013
10 BIRTHDATE 03 20 1971		11 SEX M 12 DATE 13 Hr 14 TYPE 15 SRC 16 DHR 17 STAT OI		18 19 20 21 22 23 24 25 26 27 28 29 ACCT STATE 30	
31 OCCURRENCE CODE a b 38 John Doe 1234 Main Street Philadelphia, PA 19111		32 OCCURRENCE CODE DATE 33 OCCURRENCE CODE DATE 34 OCCURRENCE CODE DATE 35 OCCURRENCE CODE DATE 36 OCCURRENCE CODE FROM THROUGH 37 39 CODE a b c d 40 CODE VALUE CODES AMOUNT 41 CODE VALUE CODES AMOUNT 42 REV. CD. 2 272 3 276 4 300 5 360 6 370 7 710 43 DESCRIPTION N482604060004 UNI Sterile Supplies IOL Laboratory Operating Room Anesthesia Recovery Room 44 HCPCS / RATE / HIPPS CODE JI097 JZ V2632 66984 00142 45 SERV. DATE 46 SERV. UNITS 47 TOTAL CHARGES 48 NON-COVERED CHARGES 49			
11 12 13 14 15 16 17 18 19 20 21 22 23 PAGE 1 OF 1		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 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 319 320 321 322 323 324 325 326 327 328 329 329 330 331 332 333 334 335 336 337 338 339 339 340 341 342 343 344 345 346 347 348 349 349 350 351 352 353 354 355 356 357 358 359 359 360 361 362 363 364 365 366 367 368 369 369 370 371 372 373 374 375 376 377 378 379 379 380 381 382 383 384 385 386 387 388 389 389 390 391 392 393 394 395 396 397 398 399 399 400 401 402 403 404 405 406 407 408 409 409 410 411 412 413 414 415 416 417 418 419 419 420 421 422 423 424 425 426 427 428 429 429 430 431 432 433 434 435 436 437 438 439 439 440 441 442 443 444 445 446 447 448 449 449 450 451 452 453 454 455 456 457 458 459 459 460 461 462 463 464 465 466 467 468 469 469 470 471 472 473 474 475 476 477 478 479 479 480 481 482 483 484 485 486 487 488 489 489 490 491 492 493 494 495 496 497 498 499 499 500 501 502 503 504 505 506 507 508 509 509 510 511 512 513 514 515 516 517 518 519 519 520 521 522 523 524 525 526 527 528 529 529 530 531 532 533 534 535 536 537 538 539 539 540 541 542 543 544 545 546 547 548 549 549 550 551 552 553 554 555 556 557 558 559 559 560 561 562 563 564 565 566 567 568 569 569 570 571 572 573 574 575 576 577 578 579 579 580 581 582 583 584 585 586 587 588 589 589 590 591 592 593 594 595 596 597 598 599 599 600 601 602 603 604 605 606 607 608 609 609 610 611 612 613 614 615 616 617 618 619 619 620 621 622 623 624 625 626 627 628 629 629 630 631 632 633 634 635 636 637 638 639 639 640 641 642 643 644 645 646 647 648 649 649 650 651 652 653 654 655 656 657 658 659 659 660 661 662 663 664 665 666 667 668 669 669 670 671 672 673 674 675 676 677 678 679 679 680 681 682 683 684 685 686 687 688 689 689 690 691 692 693 694 695 696 697 698 699 699 700 701 702 703 704 705 706 707 708 709 709 710 711 712 713 714 715 716 717 718 719 719 720 721 722 723 724 725 726 727 728 729 729 730 731 732 733 734 735 736 737 738 739 739 740 741 742 743 744 745 746 747 748 749 749 750 751 752 753 754 755 756 757 758 759 759 760 761 762 763 764 765 766 767 768 769 769 770 771 772 773 774 775 776 777 778 778 779 779 780 781 782 783 784 785 786 787 788 789 789 790 791 792 793 794 795 796 797 797 798 799 799 800 801 802 803 804 805 806 807 808 809 809 810 811 812 813 814 815 816 817 818 819 819 820 821 822 823 824 825 826 827 828 829 829 830 831 832 833 834 835 836 837 838 839 839 840 841 842 843 844 845 846 847 848 849 849 850 851 852 853 854 855 856 857 858 859 859 860 861 862 863 864 865 866 867 868 869 869 870 871 872 873 874 875 876 877 878 878 879 879 880 881 882 883 884 885 886 887 888 889 889 890 891 892 893 894 895 896 897 897 898 899 899 900 901 902 903 904 905 906 907 908 909 909 910 911 912 913 914 915 916 917 918 919 919 920 921 922 923 924 925 926 927 928 929 929 930 931 932 933 934 935 936 937 938 939 939 940 941 942 943 944 945 946 947 948 949 949 950 951 952 953 954 955 956 957 958 959 959 960 961 962 963 964 965 966 967 968 969 969 970 971 972 973 974 975 976 977 978 978 979 979 980 981 982 983 984 985 986 987 988 989 989 990 991 992 993 994 995 996 997 997 998 999 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1039 1040 1041 1042 1043 1044 1045 1046 1047 1048 1049 1049 1050 1051 1052 1053 1054 1055 1056 1057 1058 1059 1059 1060 1061 1062 1063 1064 1065 1066 1067 1068 1069 1069 1070 1071 1072 1073 1074 1075 1076 1077 1078 1078 1079 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089 1089 1090 1091 1092 1093 1094 1095 1096 1097 1097 1098 1099 1099 1100 1101 1102 1103 1104 1105 1106 1107 1108 1109 1109 1110 1111 1112 1113 1114 1115 1116 1117 1118 1119 1119 1120 1121 1122 1123 1124 1125 1126 1127 1128 1129 1129 1130 1131 1132 1133 1134 1135 1136 1137 1138 1139 1139 1140 1141 1142 1143 1144 1145 1146 1147 1148 1149 1149 1150 1151 1152 1153 1154 1155 1156 1157 1158 1159 1159 1160 1161 1162 1163 1164 1165 1166 1167 1168 1169 1169 1170 1171 1172 1173 1174 1175 1176 1177 1178 1178 1179 1179 1180 1181 1182 1183 1184 1185 1186 1187 1188 1189 1189 1190 1191 1192 1193 1194 1195 1196 1197 1197 1198 1199 1199 1200 1201 1202 1203 1204 1205 1206 1207 1208 1209 1209 1210 1211 1212 1213 1214 1215 1216 1217 1218 1219 1219 1220 1221 1222 1223 1224 1225 1226 1227 1228 1229 1229 1230 1231 1232 1233 1234 1235 1236 1237 1238 1239 1239 1240 1241 1242 1243 1244 1245 1246 1247 1248 1249 1249 1250 1251 1252 1253 1254 1255 1256 1257 1258 1259 1259 1260 1261 1262 1263 1264 1265 1266 1267 1268 1269 1269 1270 1271 1272 1273 1274 1275 1276 1277 1278 1278 1279 1279 1280 1281 1282 1283 1284 1285 1286 1287 1288 1289 1289 1290 1291 1292 1293 1294 1295 1296 1297 1297 1298 1299 1299 1300 1301 1302 1303 1304 1305 1306 1307 1308 1309 1309 1310 1311 1312 1313 1314 1315 1316 1317 1318 1319 1319 1320 1321 1322 1323 1324 1325 1326 1327 1328 1329 1329 1330 1331 1332 1333 1334 1335 1336 1337 1338 1339 1339 1340 1341 1342 1343 1344 1345 1346 1347 1348 1349 1349 1350 1351 1352 1353 1354 1355 1356 1357 1358 1359 1359 1360 1361 1362 1363 1364 1365 1366 1367 1368 1369 1369 1370 1371 1372 1373 1374 1375 1376 1377 1378 1378 1379 1379 1380 1381 1382 1383 1384 1385 1386 1387 1388 1389 1389 1390 1391 1392 1393 1394 1395 1396 1397 1397 1398 1399 1399 1400 1401 1402 1403 1404 1405 1406 1407 1408 1409 1409 1410 1411 1412 1413 1414 1415 1416 1417 1418 1419 1419 1420 1421 1422 1423 1424 1425 1426 1427 1428 1429 1429 1430 1431 1432 1433 1434 1435 1436 1437 1438 1439 1439 1440 1441 1442 1443 1444 1445 1446 1447 1448 1449 1449 1450 1451 1452 1453 1454 1455 1456 1457 1458 1459 1459 1460 1461 1462 1463 1464 1465 1466 1467 1468 1469 1469 1470 1471 1472 1473 1474 1475 1476 1477 1478 1478 1479 1479 1480 1481 1482 1483 1484 1485 1486 1487 1488 1489 1489 1490 1491 1492 1493 1494 1495 1496 1497 1497 1498 1499 1499 1500 1501 1502 1503 1504 1505 1506 1507 1508 1509 1509 1510 1511 1512 1513 1514 1515 1516 1517 1518 1519 1519 1520 1521 1522 1523 1524 1525 1526 1527 1528 1529 1529 1530 1531 1532 1533 1534 1535 1536 1537 1538 1539 1539 1540 1541 1542 1543 1544 1545 1546 1547 1548 1549 1549 1550 1551 1552 1553 1554 1555 1556 1557 1558 1559 1559 1560 1561 1562 1563 1564 1565 1566 1567 1568 1569 1569 1570 1571 1572 1573 1574 1575 1576 1577 1578 1578 1579 1579 1580 1581 1582 1583 1584 1585 1586 1587 1588 1589 1589 1590 1591 1592 1593 1594 1595 1596 1597 1597 1598 1599 1599 1600 1601 1602 1603 1604 1605 1606 1607 1608 1609 1609 1610 1611 1612 1613 1614 1615 1616 1617 1618 1619 1619 1620 1621 1622 1623 1624 1625 1626 1627 1628 1629 1629 1630 1631 1632 1633 1634 1635 1636 1637 1638 1639 1639 1640 1641 1642 1643 1644 1645 1646 1647 1648 1649 1649 1650 1651 1652 1653 1654 1655 1656 1657 1658 1659 1659 1660 1661 1662 1663 1664 1665 1666 1667 1668 1669 1669 1670 1671 1672 1673 1674 1675 1676 1677 1678 1678 1679 1679 1680 1681 1682 1683 1684 1685 1686 1687 1688 1689 1689 1690 1691 1692 1693 1694 1695 1696 1697 1697 1698 1699 1699 1700 1701 1702 1703 1704 1705 1706 1707 1708 1709 1709 1710 1711 1712 1713 1714 1715 1716 1717 1718 1719 1719 1720 1721 1722 1723 1724 1725 1726 1727 1728 1729 1729 1730 1731 1732 1733 1734 1735 1736 1737 1738 1739 1739 1740 1741 1742 1743 1744 1745 1746 1747 1748 1749 1749 1750 1751 1752 1753 1754 1755 1756 1757 1758 1759 1759 1760 1761 1762 1763 1764 1765 1766 1767 1768 1769 1769 1770 1771 1772 1773 1774 1775 1776 1777 1778 1778 1779 1779 1780 1781 1782 1783 1784 1785 1786 1787 1788 1789 1789 1790 1791 1792 1793 1794 1795 1796 1797 1797 1798 1799 1799 1800 1801 1802 1803 1804 1805 1806 1807 1808 1809 1809 1810 1811 1812 1813 1814 1815 1816 1817 1818 1819 1819 1820 1821 1822 1823 1824 1825 1826 1827 1828 1829 1829 1830 1831 1832 1833 1834 1835 1836 1837 1838 1839 1839 1840 1841 1842 1843 1844 1845 1846 1847 1848 1849 1849 1850 1851 1852 1853 1854 1855 1856 1857 1858 1859 1859 1860 1861 1862 1863 1864 1865 1866 1867 1868 1869 1869 1870 1871 1872 1873 1874 1875 1876 1877 1878 1878 1879 1879 1880 1881 1882 1883 1884 1885 1886 1887 1888 1889 1889 1890 1891 1892 1893 1894 1895 1896 1897 1897 1898 1899 1899 1900 1901 1902 1903 1904 1905 1906 1907 1908 1909 1909 1910 1911 1912 1913 1914 1915 1916 1917 1918 1919 1919 1920 1921 1922 1923 1924 1925 1926 1927 1928 1929 1929 1930 1931 1932 1933 1934 1935 1936 1937 1938 1939 1939 1940 1941 1942 1943 1944 1945 1946 			

*Note: For hospitals and ASCs using UB-04 form, it is a best practice to confirm the correct revenue code with the payer to ensure reimbursement.

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. Rayner does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. Contact 1-877-OMIDRIA (1-877-664-3742) for more information about how to submit for OMIDRIA reimbursement.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IOL=Intraocular lens; NDC=National Drug Code.

Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com



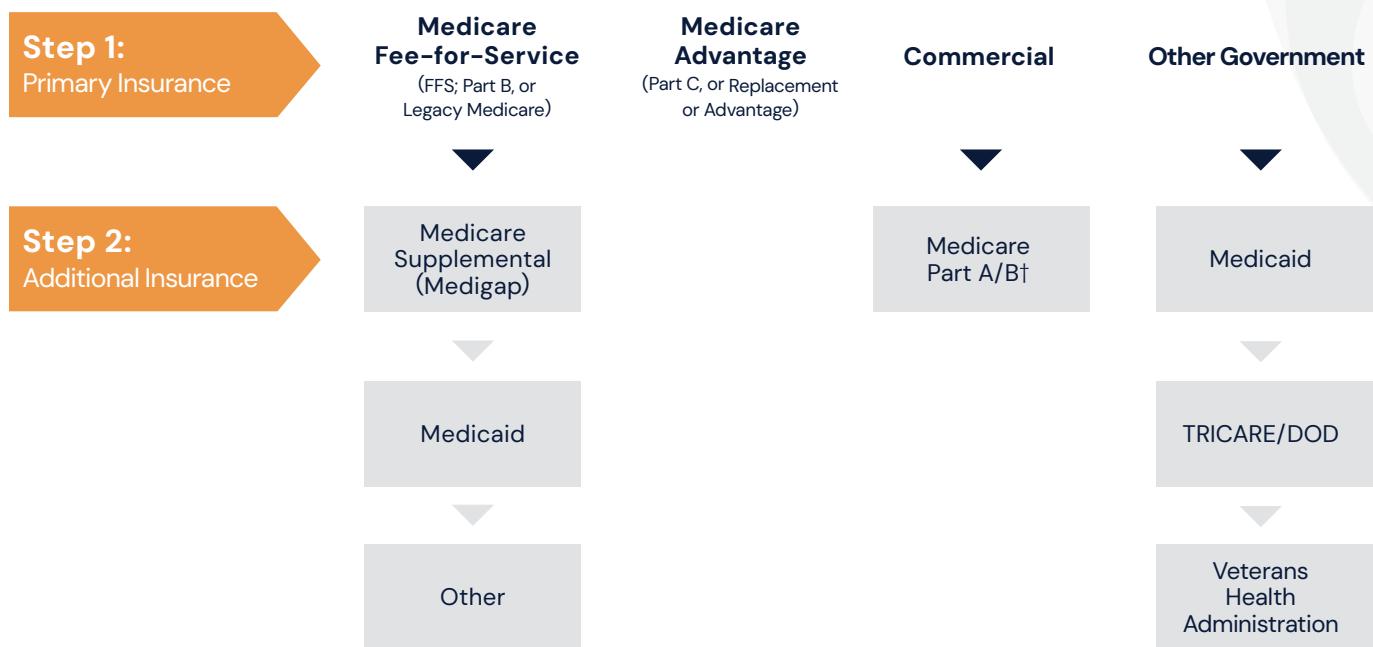
OMIDRIA®

(phenylephrine and ketorolac
intraocular solution)
1% / 0.3%

Understanding Billable Status for Patients Receiving OMIDRIA

Patient insurance benefits are typically comprised of primary and additional coverage that determine billable status

Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*



*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Patients with Medicare Part B will not be eligible for company programs.

DOD=Department of Defense; FFS=Fee-for-Service.

Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com

Medicare Fee-for-Service Billing and Reimbursement

HCPCS and NDC codes for OMIDRIA

HCPCS code ¹¹	APC	HCPCS modifier ^{14, 15}	Long descriptor ¹¹	NDC number ^{1, 20}
J1097	9324	JZ* TB**	Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL	82604-0600-04 (11-digit)

Reimbursed with separate payment

OMIDRIA has separate payment status in ASCs and HOPDs for 100% of fee-for service Medicare patients***

For OMIDRIA reimbursement in the **ASC** setting, CMS reimburses **80%** of the current Medicare Fee schedule.

For OMIDRIA in the **HOPD** setting, CMS reimburses **100%** of the current Medicare fee schedule.



The OMIDRIAAssure program offers patients options to assist with the cost of OMIDRIA:



We Pay the Difference patient reimbursement program for commercially insured patients.†



Equal Access patient assistance program for financially eligible uninsured or underinsured patients.



Field Reimbursement Managers are highly experienced in helping you navigate through the reimbursement pathway.

For personalized help, call the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), 8 AM–8 PM ET, Monday–Friday‡

* Used in ASC and HOPD

** Used in 340b Hospitals

*** OMIDRIA qualifies for separate payment across both ASC and HOPD settings as it fulfills the requirements established in the non-opioid as a surgical supply provision by CMS.

† Based on your Medicare or commercial plan selection, there may be a patient responsibility for OMIDRIA.

‡ Benefit verifications may not address contracted payer payment rates.

APC=Ambulatory Payment Classifications; ASC=Ambulatory Surgery Center; HCPCS=Healthcare Common Procedure Coding System; HOPD=Hospital Outpatient Department; NDC=National Drug Code.

Many medications require coinsurance. Healthcare providers are contractually obligated to collect applicable patient responsibility. Failure to adhere to regulations may lead to legal issues under the False Claims Act and Anti-Kickback Statute or result in audits and reimbursement penalties from insurers, including exclusion from federal healthcare programs. CMS Fraud Waste and Abuse disallows regular waive of coinsurance.

Please see Important Safety Information on page 11 and Full Prescribing Information at omidria.com



OMIDRIA®

(phenylephrine and ketorolac intraocular solution)
1% / 0.3%

Medicare Advantage Billing and Reimbursement

- In the Contract Year 2024 MA and Part D final rule published April 2023, CMS updated rules for Medicare Advantage (Part C) plans to make clear what they must cover and how they decide on what is necessary care. CMS regulations at §422.101(a) and (b) require that MA plans provide coverage of all basic benefits (that is, services covered under Medicare Parts A and B) and that MA plans must comply with Traditional Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs) applicable in the MA plan's service area.¹⁸
- In 2024, 54% of Medicare beneficiaries were enrolled in MA plans, with projections indicating an increase to 64% by 2033.¹⁹

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, Medicare Advantage plans should cover OMIDRIA, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations*
- For a Medicare Advantage patient, the specific Medicare Advantage payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for dealing with Medicare Advantage plans

- Before surgery, verify if patient has a Medicare Advantage plan
- Check if your facility-specific payer contracts follow Medicare guidelines or allow for separate payment of drugs and biologics (carve outs)
- If the plan bundles payment for OMIDRIA, share the CMS announcement regarding separate billable status

You can look up a patient's Medicare plan by entering the patient's name and date of birth in any of the following databases, among others:

- Secure Provider Online Tool (SPOT), provided by First Coast MAC
- Availity (for BCBS, Aetna, Humana)
- Palmetto e-services
- Noridian Medicare Portal

You do not need to pay a subscription fee to access these databases



EQUAL ACCESS

PATIENT ASSISTANCE PROGRAM

Assistance for financially eligible uninsured or underinsured patients

For patients who meet certain financial criteria, Rayner has established the Equal Access Patient Assistance Program as part of OMIDRIAssure.†

- Eligible patients will receive OMIDRIA at no cost
- Free vial will be sent to your facility prior to surgery
- Application for free vial must be completed and approved at least 5 days prior to date of surgery

* Rayner does not guarantee payment by any payer.

† To be eligible for the Equal Access Patient Assistance Program, patients must be enrolled prior to surgery. Program is subject to change without notice. For any patient eligible for the Equal Access Patient Assistance Program, (1) the facility receives a free vial of OMIDRIA prior to surgery, and (2) the patient's insurance carrier(s) should not be billed for OMIDRIA.

BCBS=Blue Cross Blue Shield; CMS=Centers for Medicare & Medicaid Services; FFS=Fee-for-Service; MA=Medicare Advantage.

Commercial Insurance Billing and Reimbursement

May reimburse with bundled payment

- Of all insurance types, commercial payers are the most likely to bundle payment for OMIDRIA with that for the cataract surgery procedure

Payment rate will vary by plan

- The amount commercial payers will reimburse for use of OMIDRIA may be dependent on the terms in the contract with the payer
- Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*

Identify the Payer Methodology

- How is the payment rate structured across the various payers?*
- For a commercial patient, the specific payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for commercial payers

- Check if your facility-specific payer contracts allow for separate payment of drugs and biologics (carve outs)
- Verify payer-specific use of appropriate revenue code
- Cultivate relationship with payer-provider network representative



WE PAY THE DIFFERENCE PATIENT REIMBURSEMENT PROGRAM

Assistance for patients with insufficient commercial insurance

- Rayner will cover the OMIDRIA cost difference between the facility's acquisition cost and the allowed amount of the commercially insured patient's insurance.[†]
- Visit <https://www.omidria.com/access-and-support> to download the We Pay the Difference Enrollment Form, We Pay the Difference Instruction Form, and other available resources

Reach out to our FRM team for additional support by emailing
omidriafrms@rayner.com or by calling 1-844-RAYNER1 (1-844-729-6371)

* Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

[†] OMIDRIAssure program services are subject to change without notice. The We Pay the Difference Patient Reimbursement Program patient benefit is not available for patients with any government insurance. Rayner does not guarantee reimbursement. Facility acquisition cost is determined after application of any volume-based discount. Claims must be submitted within 90 days of date of surgery. Rayner does not guarantee coverage or reimbursement.

Ordering OMIDRIA for Your Facility

How to order OMIDRIA

OMIDRIA is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution. The smallest sellable unit is a carton, which contains four (4) single-patient-use vials.

NDC#: 82604-600-04

*Use the 10-digit NDC for ordering and the 11-digit NDC for billing.

One (1) carton is the minimum order. OMIDRIA is sold only in carton quantities. OMIDRIA is not sold in individual vial quantities.



One (1) carton contains four (4) single-patient-use vials*



One (1) case contains thirty (30) cartons (120 total vials)

OMIDRIA is available through specialty distributors

McKesson Specialty Distribution[†]

Item number: 5016421 Contact number: 1-800-482-6700

McKesson Plasma and Biologics[†]

Item number: 2856201 Contact number: 1-877-625-2566

Cardinal Health Specialty Distribution[‡]

Item number: 5875778 Contact number: 1-855-855-0708

Besse Medical

Item number: 10283186 Contact number: 1-888-767-7123

AmerisourceBergen Specialty Distribution[§]

Item number: 10283069 Contact number: 1-800-746-6273

FFF Enterprises, Inc. (Offering consignment services)

Item number: OMI4060004 Contact number: 1-800-843-7477

McKesson Medical-Surgical

Item number: 1278880 Contact number: 1-855-571-2100

† For customers of McKesson full-line wholesaler division, OMIDRIA is available for purchase through McKesson Plasma and Biologics and McKesson Specialty Distribution.

‡ For customers of Cardinal full-line wholesaler division, OMIDRIA is available for purchase through Cardinal Health Specialty Distribution.

§ For customers of AmerisourceBergen Corporation full-line wholesale division, OMIDRIA is available through AmerisourceBergen specialty distribution and can be ordered using the Passport ordering platform through AmerisourceBergen.

NDC=National Drug Code.

Please see Important Safety Information on page 11
and Full Prescribing Information at omidria.com



OMIDRIA®

(phenylephrine and ketorolac
intraocular solution)
1% / 0.3%

HELPFUL RESOURCES*

www.cms.gov

- ASC (Addendum BB) and HOPD (Addendum A) Payment Rates and Updates
- CMS Quarterly Update
- MLN Matters Articles

<https://www.omidria.com/access-and-support>

- We Pay the Difference Instruction Form
- We Pay the Difference Enrollment Form
- OMIDRIAssure Patient Certification Form
- Billing and Reimbursement Guide

*Rayner does not guarantee the accuracy, completeness, or current status of information provided on third-party websites.

ASC=Ambulatory Surgery Center; ASP=average sales price; CMS=Centers for Medicare & Medicaid Services; HOPD=hospital outpatient department; MLN=Medicare Learning Network®.

INDICATIONS AND USAGE

OMIDRIA® is added to ophthalmic irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

IMPORTANT SAFETY INFORMATION

OMIDRIA must be added to irrigating solution prior to intraocular use.

OMIDRIA is contraindicated in patients with a known hypersensitivity to any of its ingredients.

Systemic exposure of phenylephrine may cause elevations in blood pressure.

Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory drugs (NSAIDs), or have a past medical history of asthma.

The most commonly reported adverse reactions at $\geq 2\%$ are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Please see the [Full Prescribing Information](#) for OMIDRIA.

You are encouraged to report Suspected Adverse Reactions to the FDA.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

References: 1. OMIDRIA [package insert]. Bellevue, WA: Rayner Surgical Inc. 2023. 2. Rosenberg ED, Nattis AS, Alevi D, et al. Visual outcomes, efficacy, and surgical complications associated with intracameral phenylephrine 1.0%/ketorolac 0.3% administered during cataract surgery. *Clin Ophthalmol*. 2018;12:21-28. 3. Al-Hashimi S, Donaldson K, Davidson R, et al. Medical and surgical management of the small pupil during cataract surgery. *J Cataract Refract Surg*. 2018;44:1032-1041. 4. Bucci FA Jr, Michalek B, Fluet AT. Comparison of the frequency of use of a pupil expansion device with and without an intracameral phenylephrine and ketorolac injection 1%/0.3% at the time of routine cataract surgery. *Clin Ophthalmol*. 2017;11:1039-1043. 5. Matossian C. Clinical and economic outcomes in cataract surgery using phenylephrine 1.0%-Ketorolac 0.3% in a real-world setting. Abstract presented at: Annual Meeting of the American Society of Cataract and Refractive Surgeons (ASCRS); April 16, 2018; Washington, DC. Course 5219. 6. Walter K, Delwadia N, Cohen J. Continuous intracameral phenylephrine–ketorolac irrigation for miosis prevention in femtosecond laser-assisted cataract surgery: reduction in surgical time and iris manipulation. *J Cataract Refract Surg*. 2019;45(4):465-469. 7. Visco D. Effect of phenylephrine/ketorolac on iris fixation ring use and surgical times in patients at risk of intraoperative miosis. *Clin Ophthalmol*. 2018;12:301-305. 8. Silverstein SM, Rana VK, Stephens R, et al. Effect of phenylephrine 1.0%-ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg*. 2018;44(9):1103-1108. 9. Visco DM, Bedi R. Effect of intracameral phenylephrine 1.0%-ketorolac 0.3% on postoperative cystoid macular edema, iritis, pain, and photophobia after cataract surgery. *J Cataract Refract Surg*. 2020;46(6):867-872. 10. Donnenfeld ED, Hovanesian JA, Malik AG, Wong A. A randomized, prospective, observer-masked study comparing dropless treatment regimen using intracanalicular dexamethasone insert, intracameral ketorolac, and intracameral moxifloxacin versus conventional topical therapy to control postoperative pain and inflammation in cataract surgery. *Clin Ophthalmol*. 2023;17:2349-2356. 11. 2025 Healthcare Common Procedure Coding System. Accessed December 29, 2025. <https://hcpcs.codes/j-codes/J1097/> 12. Billing and Coding: Cataract Extraction (including Complex Cataract Surgery) A58592, Medicare Coverage Database CMS.gov; Billing and Coding: Use of Laterality Modifiers A56860, Medicare Coverage Database CMS.gov 13. Jagmin CL, Levy BS, Ashley SM eds, et al. CPT 2025 Professional Edition. American Medical Association. 2024. 14. New JZ Claims Modifier for Certain Medicare Part B Drugs. MM 13056. CR 13056. CMS Medicare Learning Network June 2, 2023 15. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. MLN Fact Sheet MLN4800856. CMS Medicare Learning Network, November 2024. 16. Professional Paper Claim Form (CMS-1500). CMS.gov. September 10, 2024. 17. CMS-1450 Medicare Uniform Institutional Provider Bill. CMS.gov. June 6, 2023. 18. Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Federal Register April 12, 2023. <https://www.federalregister.gov/d/2023-07115/p-728> accessed June 9, 2025. 19. Medicare Advantage in 2024: enrollment Update and Key Trends. Meredith Freed, JF Biniek, A. Domico and T Neuman. KFF Aug 8th, 2024. 20. U.S. Food & Drug National Drug Code Directory. Accessed January 5, 2026 <https://www.accessdata.fda.gov/scripts/cder/ndc/>



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OMIDRIA® safely and effectively. See full prescribing information for OMIDRIA.

OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3%, for addition to ocular irrigating solution
Initial U.S. Approval: 2014

INDICATIONS AND USAGE

OMIDRIA is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for:

- Maintaining pupil size by preventing intraoperative miosis (1)
- Reducing postoperative pain (1)

OMIDRIA is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement.

DOSAGE AND ADMINISTRATION

- Each vial of OMIDRIA must be diluted prior to use for administration to a single patient undergoing cataract surgery or intraocular lens replacement.
- Dilute 4 mL of OMIDRIA in 500 mL of ocular irrigating solution. Irrigation solution is to be used as needed for the surgical procedure. (2)

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Elevated Blood Pressure

5.2 Cross-Sensitivity or Hypersensitivity

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

10 OVERDOSAGE

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.3 Pharmacokinetics

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Omidria® is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.

2 DOSAGE AND ADMINISTRATION

Omidria must be diluted prior to intraocular use. For administration to patients undergoing cataract surgery or intraocular lens replacement, 4 mL of Omidria is diluted in 500 mL of ocular irrigating solution. Irrigation solution is to be used as needed for the surgical procedure for a single patient.

The storage period for the diluted product is not more than 4 hours at room temperature or 24 hours under refrigerated conditions.

Do not use if the solution is cloudy or if it contains particulate matter.

3 DOSAGE FORMS AND STRENGTHS

Omidria is an intraocular solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL (0.3% w/v) of ketorolac for use in a single patient.

4 CONTRAINDICATIONS

Omidria is contraindicated in patients with a known hypersensitivity to any of its ingredients.

5 WARNINGS AND PRECAUTIONS

5.1 Elevated Blood Pressure

Systemic exposure to phenylephrine can cause elevations in blood pressure.

5.2 Cross-Sensitivity or Hypersensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory drugs (NSAIDs). There have been reports of bronchospasm or exacerbation of asthma associated with the use of ketorolac in patients who either have a known hypersensitivity to aspirin/NSAIDs or a past medical history of asthma. Therefore, use Omidria with caution in individuals who have previously exhibited sensitivities to these drugs.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Table 1 shows frequently reported ocular adverse reactions with an incidence of $\geq 2\%$ of adult patients as seen in the combined clinical trial results from three randomized, placebo-controlled studies [see Clinical Pharmacology (12.3)].

DOSAGE FORMS AND STRENGTHS

Intracocular solution containing phenylephrine 10.16 mg/mL (1%) and ketorolac 2.88 mg/mL (0.3%) for use in a single patient. (3)

CONTRAINDICATIONS

Hypersensitivity to any component of this product (4)

WARNINGS AND PRECAUTIONS

Systemic exposure to phenylephrine may cause elevations in blood pressure. (5.1)

ADVERSE REACTIONS

The most common reported adverse reactions ($\geq 2\%$) are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Rayner Surgical Inc. at 1-877-OMIDRIA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 04/2023

Table 1: Ocular Adverse Reactions Reported by $\geq 2\%$ of Adult Patients

MedDRA Preferred Term	Placebo (N=462)	Omidria (N=459)
	n (%)	n (%)
Ocular Events		
Anterior Chamber Inflammation	102 (22%)	111 (24%)
Intraocular Pressure Increased	15 (3%)	20 (4%)
Posterior Capsule Opacification	16 (4%)	18 (4%)
Eye Irritation	6 (1%)	9 (2%)
Foreign Body Sensation in Eyes	11 (2%)	8 (2%)

In a safety study that enrolled 72 pediatric patients up to 3 years old, no overall difference in safety was observed between pediatric and adult patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Omidria use in pregnant women or animals to inform any drug-associated risks. Oral administration of ketorolac to rats during late gestation produced dystocia and increased pup mortality at a dose 740-times the plasma exposure at the recommended human ophthalmic dose (RHOD). Since human systemic exposure to Omidria following a lens replacement procedure is low [see Clinical Pharmacology (12.3)], the applicability of animal findings to the risk of Omidria in humans during pregnancy is unclear. Omidria should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Premature closure of the ductus arteriosus in the fetus has occurred with third trimester use of oral and injectable NSAIDs. Ketorolac plasma concentrations are detectable following ocular Omidria administration [see Clinical Pharmacology (12.3)]. The use of Omidria during late pregnancy should be avoided.

Data

Animal Data

No well-controlled animal reproduction studies have been conducted with Omidria or phenylephrine.

Ketorolac, administered during organogenesis, did not cause embryofetal abnormalities or mortality in rabbits or rats at oral doses of 3.6 mg/kg/day and 10 mg/kg/day, respectively. These doses produced systemic exposure that is 1150 times and 4960 times the plasma exposure (based on C_{max}) at the RHOD, respectively. When administered to rats during late gestation (after Day 17 of gestation) at oral doses up to 1.5 mg/kg/day (740 times the plasma exposure at the RHOD), ketorolac produced dystocia and increased pup mortality.

8.2 Lactation

Risk Summary

There are no data on the presence of Omidria in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to Omidria, following a lens replacement procedure is low [see Clinical Pharmacology (12.3)]. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omidria and any potential adverse effects on the breastfed child from Omidria.

8.4 Pediatric Use

The safety and effectiveness of Omidria have been established in the pediatric population from neonates to adolescents (birth to younger than 17 years). Use of Omidria in this population is supported by evidence from adequate and well-controlled studies of Omidria in adults with additional data from a single active-controlled safety study in pediatric patients up to 3 years old (see Clinical Studies (14)).

No overall differences in safety were observed between pediatric and adult patients.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and adult patients.

10 OVERDOSAGE

Systemic overdosage of phenylephrine may cause a rise in blood pressure. It may also cause headache, anxiety, nausea, vomiting, and ventricular arrhythmias. Supportive care is recommended.

11 DESCRIPTION

Omidria is a sterile aqueous solution, containing the α_1 -adrenergic receptor agonist phenylephrine HCl and the nonsteroidal anti-inflammatory ketorolac tromethamine, for addition to ocular irrigating solution.

The descriptions and structural formulae are:

Phenylephrine Hydrochloride Drug Substance:

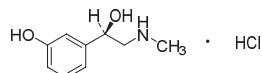
Common Name: phenylephrine hydrochloride

Chemical Name: (-)-m-Hydroxy- α -[(methylamino)methyl]benzyl alcohol hydrochloride

Molecular Formula: $C_9H_{13}NO_2 \cdot HCl$

Molecular Weight: 203.67 g/mole

Figure 1: Chemical Structure for Phenylephrine HCl



Ketorolac Tromethamine Drug Substance:

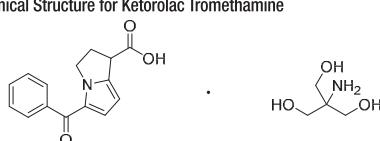
Common Name: ketorolac tromethamine

Chemical Name: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid:2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)

Molecular Formula: $C_{14}H_{13}NO_3 \cdot C_3H_6NO_3$

Molecular Weight: 376.40 g/mole

Figure 2: Chemical Structure for Ketorolac Tromethamine



Omidria is a clear, colorless to slightly yellow, sterile solution concentrate with a pH of approximately 6.3.

Each vial of Omidria contains:

Actives: phenylephrine hydrochloride 12.4 mg/mL equivalent to 10.16 mg/mL of phenylephrine and ketorolac tromethamine 4.24 mg/mL equivalent to 2.88 mg/mL of ketorolac.

Inactives: citric acid monohydrate; sodium citrate dihydrate; water for injection; may include sodium hydroxide and/or hydrochloric acid for pH adjustment.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The two active pharmaceutical ingredients (API) in Omidria, phenylephrine and ketorolac, act to maintain pupil size by preventing intraoperative miosis, and reducing postoperative pain.

Phenylephrine is an α_1 -adrenergic receptor agonist and, in the eye, acts as a mydriatic agent by contracting the radial muscle of the iris. Ketorolac is a nonsteroidal anti-inflammatory that inhibits both cyclooxygenase enzymes (COX-1 and COX-2), resulting in a decrease in tissue concentrations of prostaglandins to reduce pain due to surgical trauma. Ketorolac, by inhibiting prostaglandin synthesis secondary to ocular surgical insult or direct mechanical stimulation of the iris, also prevents surgically induced miosis.

12.3 Pharmacokinetics

In a pharmacokinetic study evaluating Omidria, systemic exposure to both phenylephrine and ketorolac was low or undetectable.

A single-dose of Omidria as part of the irrigation solution was administered in 14 patients during lens replacement surgery. The volume of irrigation solution used during surgery ranged between 150 mL to 300 mL (median 212.5 mL). Detectable phenylephrine plasma concentrations were observed in one of 14 patients (range 1.2 to 1.4 ng/mL) during the first 2 hours after the initiation of Omidria administration. The observed phenylephrine plasma concentrations could not be distinguished from the preoperative administration of phenylephrine 2.5% ophthalmic solution prior to exposure to Omidria.

Ketorolac plasma concentrations were detected in 10 of 14 patients (range 1.0 to 4.2 ng/mL) during the first 8 hours after the initiation of Omidria administration. The maximum ketorolac concentration was 15 ng/mL at 24 hours after the initiation of Omidria administration, which may have been due to application of postoperative ketorolac ophthalmic solution.

14 CLINICAL STUDIES

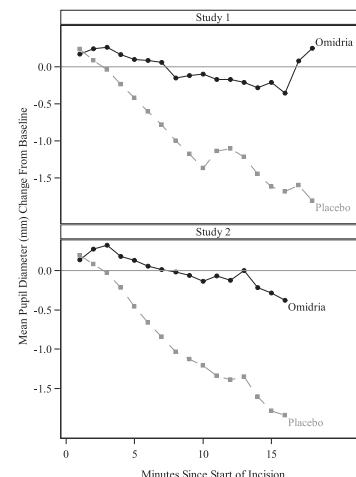
Studies in Adults

The efficacy and safety of Omidria were evaluated in two Phase 3, randomized, multicenter, double-masked, placebo-controlled clinical trials in 808 adult patients undergoing cataract surgery or intraocular lens replacement.

Patients were randomized to either Omidria or placebo. Patients were treated with preoperative topical mydriatic and anesthetic agents. Pupil diameter was measured throughout the surgical procedure. Postoperative pain was evaluated by self-administered 0-100 mm visual analog scales (VAS).

Mydriasis was maintained in the Omidria-treated groups while the placebo-treated groups experienced progressive constriction.

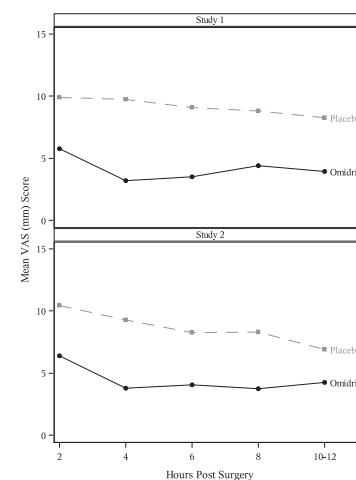
Figure 3: Intraoperative Pupil Diameter (mm) Change-from-Baseline



At the end of cortical clean-up, 23% of placebo-treated patients and 4% of Omidria-treated patients had a pupil diameter less than 6 mm ($p < 0.01$).

Pain during the initial 10-12 hours postoperatively was statistically significantly less in the Omidria-treated groups than in the placebo-treated groups.

Figure 4: Postoperative Mean Visual Analog Scale (VAS) Scores for Pain



During the 10-12 hours postoperatively, 26% of Omidria-treated patients reported no pain (VAS = 0 at all timepoints) while 17% of placebo-treated patients reported no pain ($p < 0.01$).

Study in Pediatric Patients

The safety of Omidria was evaluated in a single, randomized, multicenter, double-masked, active-controlled clinical study in 72 pediatric patients up to 3 years old undergoing cataract surgery with or without intraocular lens replacement.

Patients were randomized to either Omidria or phenylephrine. Patients were treated with preoperative topical mydriatic and anesthetic agents. As in the adult studies, mydriasis was maintained in the Omidria-treated group. No overall differences in safety were observed between pediatric and adult patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

Omidria (phenylephrine and ketorolac intraocular solution) 1%/0.3% is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution, for addition to ocular irrigating solution.

Omidria is supplied in a multi-pack containing:

4 vials: NDC 82604-600-04 or

10 vials: NDC 82604-600-10

Storage: Store at 20° to 25°C (68° to 77°F). Protect from light.

17 PATIENT COUNSELING INFORMATION

Inform patients that they may experience sensitivity to light.

Rayner Surgical Inc.

Suite 102, 14335 NE 24th Street

Bellevue, WA 98007

Patented product see

www.rayner.com/patents

for further details.

© Rayner 2023

OMIDRIA® and the OMIDRIA® logo are registered trademarks of Rayner Surgical Inc.

640069

Revised: 04/2023

US-OM-2300042 04/23