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1415 **Medication Guide**

1416 **PAXIL® (PAX-il)**

1417 **(paroxetine hydrochloride)**

1418 **Tablets and Oral Suspension**

1419
1420 Read the Medication Guide that comes with PAXIL before you start taking it and each time you
1421 get a refill. There may be new information. This Medication Guide does not take the place of
1422 talking to your healthcare provider about your medical condition or treatment. Talk with your
1423 healthcare provider if there is something you do not understand or want to learn more about.

1424
1425 **What is the most important information I should know about PAXIL?**

1426 PAXIL and other antidepressant medicines may cause serious side effects, including:

1427 **1. Suicidal thoughts or actions:**

- 1428 • **PAXIL and other antidepressant medicines may increase suicidal thoughts or**
1429 **actions** in some children, teenagers, or young adults within the **first few months of**
1430 **treatment or when the dose is changed.**
- 1431 • Depression or other serious mental illnesses are the most important causes of suicidal
1432 thoughts or actions.
- 1433 • Watch for these changes and call your healthcare provider right away if you notice:
- 1434 • New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially
1435 if severe.
- 1436 • Pay particular attention to such changes when PAXIL is started or when the dose is
1437 changed.

1438 Keep all follow-up visits with your healthcare provider and call between visits if you are worried
1439 about symptoms.

1440 **Call your healthcare provider right away if you have any of the following symptoms,**
1441 **or call 911 if an emergency, especially if they are new, worse, or worry you:**

- 1442 • attempts to commit suicide
- 1443 • acting on dangerous impulses
- 1444 • acting aggressive or violent
- 1445 • thoughts about suicide or dying
- 1446 • new or worse depression
- 1447 • new or worse anxiety or panic attacks
- 1448 • feeling agitated, restless, angry, or irritable
- 1449 • trouble sleeping
- 1450 • an increase in activity or talking more than what is normal for you
- 1451 • other unusual changes in behavior or mood

1452 **Call your healthcare provider right away if you have any of the following symptoms, or call**

- 1453 **911 if an emergency. PAXIL may be associated with these serious side effects:**
- 1454 **2. Serotonin Syndrome or Neuroleptic Malignant Syndrome-like reactions. This**
- 1455 **condition can be life-threatening and may include:**
- 1456 • agitation, hallucinations, coma, or other changes in mental status
- 1457 • coordination problems or muscle twitching (overactive reflexes)
- 1458 • racing heartbeat, high or low blood pressure
- 1459 • sweating or fever
- 1460 • nausea, vomiting, or diarrhea
- 1461 • muscle rigidity
- 1462 **3. Severe allergic reactions:**
- 1463 • trouble breathing
- 1464 • swelling of the face, tongue, eyes, or mouth
- 1465 • rash, itchy welts (hives), or blisters, alone or with fever or joint pain
- 1466 **4. Abnormal bleeding:** PAXIL and other antidepressant medicines may increase your risk of
- 1467 bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin[®],
- 1468 Jantoven[®]), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen),
- 1469 or aspirin.
- 1470 **5. Seizures or convulsions**
- 1471 **6. Manic episodes:**
- 1472 • greatly increased energy
- 1473 • severe trouble sleeping
- 1474 • racing thoughts
- 1475 • reckless behavior
- 1476 • unusually grand ideas
- 1477 • excessive happiness or irritability
- 1478 • talking more or faster than usual
- 1479 **7. Changes in appetite or weight.** Children and adolescents should have height and weight
- 1480 monitored during treatment.
- 1481 **8. Low salt (sodium) levels in the blood.** Elderly people may be at greater risk for this.
- 1482 Symptoms may include:
- 1483 • headache
- 1484 • weakness or feeling unsteady
- 1485 • confusion, problems concentrating or thinking, or memory problems
- 1486 **Do not stop PAXIL without first talking to your healthcare provider.** Stopping PAXIL too
- 1487 quickly may cause serious symptoms including:
- 1488 • anxiety, irritability, high or low mood, feeling restless, or changes in sleep habits
- 1489 • headache, sweating, nausea, dizziness
- 1490 • electric shock-like sensations, shaking, confusion
- 1491
- 1492 **What is PAXIL?**

1493 PAXIL is a prescription medicine used to treat depression. It is important to talk with your
1494 healthcare provider about the risks of treating depression and also the risks of not treating it. You
1495 should discuss all treatment choices with your healthcare provider. PAXIL is also used to treat:

- 1496 • Major Depressive Disorder (MDD)
- 1497 • Obsessive Compulsive Disorder (OCD)
- 1498 • Panic Disorder
- 1499 • Social Anxiety Disorder
- 1500 • Generalized Anxiety Disorder (GAD)
- 1501 • Posttraumatic Stress Disorder (PTSD)

1502 Talk to your healthcare provider if you do not think that your condition is getting better with
1503 treatment using PAXIL.

1504

1505 **Who should not take PAXIL?**

1506 Do not take PAXIL if you:

- 1507 • are allergic to paroxetine or any of the ingredients in PAXIL. See the end of this Medication
1508 Guide for a complete list of ingredients in PAXIL.
- 1509 • take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if
1510 you are not sure if you take an MAOI, including the antibiotic linezolid.
- 1511 • Do not take an MAOI within 2 weeks of stopping PAXIL unless directed to do so by your
1512 physician.
- 1513 • Do not start PAXIL if you stopped taking an MAOI in the last 2 weeks unless directed to do
1514 so by your physician.
- 1515 • **People who take PAXIL close in time to an MAOI may have serious or even life-**
1516 **threatening side effects. Get medical help right away if you have any of these**
1517 **symptoms:**
 - 1518 • high fever
 - 1519 • uncontrolled muscle spasms
 - 1520 • stiff muscles
 - 1521 • rapid changes in heart rate or blood pressure
 - 1522 • confusion
 - 1523 • loss of consciousness (pass out)
- 1524 • **take MELLARIL[®] (thioridazine). Do not take MELLARIL[®] together with PAXIL**
1525 **because this can cause serious heart rhythm problems or sudden death.**
- 1526 • **take the antipsychotic medicine pimozide (ORAP[®]) because this can cause serious heart**
1527 **problems.**

1528

1529 **What should I tell my healthcare provider before taking PAXIL? Ask if you are not sure.**

1530 Before starting PAXIL, tell your healthcare provider if you:

- 1531 • **are pregnant, may be pregnant, or plan to become pregnant.** There is a possibility that
1532 PAXIL may harm your unborn baby, including an increased risk of birth defects, particularly
1533 heart defects. Other risks may include a serious condition in which there is not enough
1534 oxygen in the baby’s blood. Your baby may also have certain other symptoms shortly after
1535 birth. Premature births have also been reported in some women who used PAXIL during
1536 pregnancy.
- 1537 • **are breastfeeding.** PAXIL passes into your milk. Talk to your healthcare provider about the
1538 best way to feed your baby while taking PAXIL.
- 1539 • are taking certain drugs such as:
- 1540 • triptans used to treat migraine headache
 - 1541 • other antidepressants (SSRIs, SNRIs, tricyclics, or lithium) or antipsychotics
 - 1542 • drugs that affect serotonin, such as lithium, tramadol, tryptophan, St. John’s wort
 - 1543 • certain drugs used to treat irregular heart beats
 - 1544 • certain drugs used to treat schizophrenia
 - 1545 • certain drugs used to treat HIV infection
 - 1546 • certain drugs that affect the blood, such as warfarin, aspirin, and ibuprofen
 - 1547 • certain drugs used to treat epilepsy
 - 1548 • atomoxetine
 - 1549 • cimetidine
 - 1550 • fentanyl
 - 1551 • metoprolol
 - 1552 • pimozide
 - 1553 • procyclidine
 - 1554 • tamoxifen
- 1555 • have liver problems
- 1556 • have kidney problems
- 1557 • have heart problems
- 1558 • have or had seizures or convulsions
- 1559 • have bipolar disorder or mania
- 1560 • have low sodium levels in your blood
- 1561 • have a history of a stroke
- 1562 • have high blood pressure
- 1563 • have or had bleeding problems
- 1564 • have glaucoma (high pressure in the eye)

1565

1566 **Tell your healthcare provider about all the medicines you take,** including prescription and
1567 non-prescription medicines, vitamins, and herbal supplements. PAXIL and some medicines may
1568 interact with each other, may not work as well, or may cause serious side effects.

1569 Your healthcare provider or pharmacist can tell you if it is safe to take PAXIL with your other
1570 medicines. Do not start or stop any medicine while taking PAXIL without talking to your
1571 healthcare provider first.

1572 If you take PAXIL, you should not take any other medicines that contain paroxetine, including
1573 PAXIL CR and PEXEVA[®] (paroxetine mesylate).

1574

1575 **How should I take PAXIL?**

- 1576 • Take PAXIL exactly as prescribed. Your healthcare provider may need to change the dose of
1577 PAXIL until it is the right dose for you.
- 1578 • PAXIL may be taken with or without food.
- 1579 • If you are taking PAXIL Oral Suspension, shake the suspension well before use.
- 1580 • If you miss a dose of PAXIL, take the missed dose as soon as you remember. If it is almost
1581 time for the next dose, skip the missed dose and take your next dose at the regular time. Do
1582 not take two doses of PAXIL at the same time.
- 1583 • If you take too much PAXIL, call your healthcare provider or poison control center right
1584 away, or get emergency treatment.
- 1585 • Do not stop taking PAXIL suddenly without talking to your doctor (unless you have
1586 symptoms of a severe allergic reaction). If you need to stop taking PAXIL, your healthcare
1587 provider can tell you how to safely stop taking it.

1588

1589 **What should I avoid while taking PAXIL?**

1590 PAXIL can cause sleepiness or may affect your ability to make decisions, think clearly, or react
1591 quickly. You should not drive, operate heavy machinery, or do other dangerous activities until
1592 you know how PAXIL affects you. Do not drink alcohol while using PAXIL.

1593

1594 **What are possible side effects of PAXIL?**

1595 PAXIL may cause serious side effects, including all of those described in the section entitled
1596 “What is the most important information I should know about PAXIL?”

1597 Common possible side effects in people who take PAXIL include:

- 1598 • nausea
- 1599 • sleepiness
- 1600 • weakness
- 1601 • dizziness
- 1602 • feeling anxious or trouble sleeping
- 1603 • sexual problems
- 1604 • sweating
- 1605 • shaking
- 1606 • not feeling hungry

- 1607 • dry mouth
- 1608 • constipation
- 1609 • infection
- 1610 • yawning

1611 Tell your healthcare provider if you have any side effect that bothers you or that does not go
1612 away. These are not all the possible side effects of PAXIL. For more information, ask your
1613 healthcare provider or pharmacist.

1614 **CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY**
1615 **REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088 or 1-800-332-1088.**

1616

1617 **How should I store PAXIL?**

- 1618 • Store PAXIL Tablets at room temperature between 59° and 86°F (15° and 30°C).
- 1619 • Store PAXIL Oral Suspension at or below 77°F (25°C).
- 1620 • Keep PAXIL away from light.
- 1621 • Keep bottle of PAXIL closed tightly.

1622 **Keep PAXIL and all medicines out of the reach of children.**

1623

1624 **General information about PAXIL**

1625 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
1626 Do not use PAXIL for a condition for which it was not prescribed. Do not give PAXIL to other
1627 people, even if they have the same condition. It may harm them.

1628

1629 This Medication Guide summarizes the most important information about PAXIL. If you would
1630 like more information, talk with your healthcare provider. You may ask your healthcare provider
1631 or pharmacist for information about PAXIL that is written for healthcare professionals.

1632

1633 For more information about PAXIL call 1-888-825-5249 or go to www.us.gsk.com.

1634

1635 **What are the ingredients in PAXIL?**

1636 **Active ingredient:** paroxetine hydrochloride

1637 **Inactive ingredients in tablets:** dibasic calcium phosphate dihydrate, hypromellose, magnesium
1638 stearate, polyethylene glycols, polysorbate 80, sodium starch glycolate, titanium dioxide, and 1
1639 or more of the following: D&C Red No. 30 aluminum lake, D&C Yellow No. 10 aluminum lake,
1640 FD&C Blue No. 2 aluminum lake, FD&C Yellow No. 6 aluminum lake.

1641 **Inactive ingredients in suspension for oral administration:** polacrillin potassium,
1642 microcrystalline cellulose, propylene glycol, glycerin, sorbitol, methylparaben, propylparaben,
1643 sodium citrate dihydrate, citric acid anhydrous, sodium saccharin, flavorings, FD&C Yellow
1644 No. 6 aluminum lake, and simethicone emulsion, USP.

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1646 PAXIL and PAXIL CR are registered trademarks of GlaxoSmithKline. The other brands listed
1647 are trademarks of their respective owners and are not trademarks of GlaxoSmithKline. The
1648 makers of these brands are not affiliated with and do not endorse GlaxoSmithKline or its
1649 products.

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1651 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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1657 July 2011

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