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869 Read this Medication Guide carefully before you start using ZYBAN and each time you get a
870 refill. There may be new information. This information does not take the place of talking with
871 your doctor about your medical condition or your treatment. If you have any questions about
872 ZYBAN, ask your doctor or pharmacist.

873

874 **IMPORTANT: Be sure to read the section of this Medication Guide beginning with “What**
875 **is the most important information I should know about ZYBAN?” It contains important**
876 **information about this medication. It immediately follows the next section called “About**
877 **Using Antidepressants in Children and Teenagers.”**

878

879

About Using Antidepressants in Children and Teenagers

880

881 **What is the most important information I should know if my child is being prescribed an**
882 **antidepressant?**

883

884 Parents or guardians need to think about 4 important things when their child is prescribed an
885 antidepressant:

886

1. There is a risk of suicidal thoughts or actions

887

2. How to try to prevent suicidal thoughts or actions in your child

888

3. You should watch for certain signs if your child is taking an antidepressant

889

4. There are benefits and risks when using antidepressants

890

1. There is a Risk of Suicidal Thoughts or Actions

891

892 Children and teenagers sometimes think about suicide, and many report trying to kill themselves.

893

894 Antidepressants increase suicidal thoughts and actions in some children and teenagers. But
895 suicidal thoughts and actions can also be caused by depression, a serious medical condition that
896 is commonly treated with antidepressants. Thinking about killing yourself or trying to kill
897 yourself is called *suicidality* or *being suicidal*.

898

899 A large study combined the results of 24 different studies of children and teenagers with
900 depression or other illnesses. In these studies, patients took either a placebo (sugar pill) or an
901 antidepressant for 1 to 4 months. ***No one committed suicide in these studies***, but some patients
902 became suicidal. On sugar pills, 2 out of every 100 became suicidal. On the antidepressants, 4
903 out of every 100 patients became suicidal.

904

905 **For some children and teenagers, the risks of suicidal actions may be especially high.** These
906 include patients with
907

908 • Bipolar illness (sometimes called manic-depressive illness)

909 • A family history of bipolar illness

910 • A personal or family history of attempting suicide

911 If any of these are present, make sure you tell your healthcare provider before your child takes an
912 antidepressant.

913

914 **2. How to Try to Prevent Suicidal Thoughts and Actions**

915

916 To try to prevent suicidal thoughts and actions in your child, pay close attention to changes in her
917 or his moods or actions, especially if the changes occur suddenly. Other important people in your
918 child's life can help by paying attention as well (e.g., your child, brothers and sisters, teachers,
919 and other important people). The changes to look out for are listed in Section 3, on what to watch
920 for.

921

922 Whenever an antidepressant is started or its dose is changed, pay close attention to your child.

923 After starting an antidepressant, your child should generally see his or her healthcare provider:

924

- Once a week for the first 4 weeks

925

- Every 2 weeks for the next 4 weeks

926

- After taking the antidepressant for 12 weeks

927

- After 12 weeks, follow your healthcare provider's advice about how often to come back

928

- More often if problems or questions arise (see Section 3)

929

930 You should call your child's healthcare provider between visits if needed.

931

932 **3. You Should Watch For Certain Signs if Your Child is Taking an Antidepressant**

933

934 Contact your child's healthcare provider *right away* if your child exhibits any of the following
935 signs for the first time, or they seem worse, or worry you, your child, or your child's teacher:

936

- Thoughts about suicide or dying

937

- Attempts to commit suicide

938

- New or worse depression

939

- New or worse anxiety

940

- Feeling very agitated or restless

941

- Panic attacks

942

- Difficulty sleeping (insomnia)

943

- New or worse irritability

944

- Acting aggressive, being angry, or violent

945

- Acting on dangerous impulses

946

- An extreme increase in activity and talking

947

- Other unusual changes in behavior or mood

948

949 Never let your child stop taking an antidepressant without first talking to his or her healthcare
950 provider. Stopping an antidepressant suddenly can cause other symptoms.

951

952 4. There are Benefits and Risks When Using Antidepressants

953

954 Antidepressants are used to treat depression and other illnesses. Depression and other illnesses
955 can lead to suicide. In some children and teenagers, treatment with an antidepressant increases
956 suicidal thinking or actions. It is important to discuss all the risks of treating depression and also
957 the risks of not treating it. You and your child should discuss all treatment choices with your
958 healthcare provider, not just the use of antidepressants.

959

960 Other side effects can occur with antidepressants (see section below).

961

962 Of all antidepressants, only fluoxetine (PROZAC®)* has been FDA approved to treat pediatric
963 depression.

964

965 For obsessive compulsive disorder in children and teenagers, FDA has approved only fluoxetine
966 (PROZAC®)*, sertraline (ZOLOFT®)*, fluvoxamine (LUVOX®)*, and clomipramine
967 (ANAFRANIL®)*.

968

969 Your healthcare provider may suggest other antidepressants based on the past experience of your
970 child or other family members.

971

972 Is this all I need to know if my child is being prescribed an antidepressant?

973

974 No. This is a warning about the risk of suicidality. Other side effects can occur with
975 antidepressants. Be sure to ask your healthcare provider to explain all the side effects of the
976 particular drug he or she is prescribing. Also ask about drugs to avoid when taking an
977 antidepressant. Ask your healthcare provider or pharmacist where to find more information.

978

979 What is the most important information I should know about ZYBAN?

980

981 There is a chance of having a seizure (convulsion, fit) with ZYBAN, especially in people:

982

- with certain medical problems.
- who take certain medicines.

983

984
985 The chance of having seizures increases with higher doses of ZYBAN. For more information,
986 see the sections “Who should not take ZYBAN?” and “What should I tell my doctor before using
987 ZYBAN?” Tell your doctor about all of your medical conditions and all the medicines you take.

988 **Do not take any other medicines while you are using ZYBAN unless your doctor has said it**
989 **is okay to take them.**

990

991 **If you have a seizure while taking ZYBAN, stop taking the tablets and call your doctor**
992 **right away.** Do not take ZYBAN again if you have a seizure.

993

994 What is important information I should know and share with my family about taking
995 antidepressants?

996 Although ZYBAN is not a treatment for depression, it contains the same active ingredient as the
997 antidepressant medications WELLBUTRIN[®], WELLBUTRIN SR[®], and WELLBUTRIN XL[®].
998 Therefore, you should be aware of the following information. Patients taking antidepressants,
999 and their families, should watch out for worsening depression or thoughts of suicide. Also watch
1000 out for sudden or severe changes in feelings such as feeling anxious, agitated, panicky, irritable,
1001 hostile, aggressive, impulsive, severely restless, overly excited and hyperactive, not being able to
1002 sleep, or other unusual changes in behavior. If this happens, especially at the beginning of
1003 antidepressant treatment or after a change in dose, call your doctor. For additional information,
1004 see section above entitled "About Using Antidepressants in Children and Teenagers." ZYBAN
1005 has not been studied in children under the age of 18 and is not approved for use in children and
1006 teenagers.

1007 **What is ZYBAN?**

1008 ZYBAN is a prescription medicine to help people quit smoking. Studies have shown that more
1009 than one third of people quit smoking for at least 1 month while taking ZYBAN and participating
1010 in a patient support program. For many patients, ZYBAN reduces withdrawal symptoms and the
1011 urge to smoke. ZYBAN should be used with a patient support program. It is important to
1012 participate in the behavioral program, counseling, or other support program your health care
1013 professional recommends.

1014 **Who should not take ZYBAN?**

1015 **Do not take ZYBAN if you:**

- 1016 • have or had a seizure disorder or epilepsy.
- 1017 • **are taking WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, or any other**
1018 **medicines that contain bupropion hydrochloride.** Bupropion is the same active ingredient
1019 that is in ZYBAN.
- 1020 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these
1021 make you sleepy) or benzodiazepines and you stop using them all of a sudden.
- 1022 • have taken within the last 14 days medicine for depression called a monoamine oxidase
1023 inhibitor (MAOI), such as NARDIL^{®*} (phenelzine sulfate), PARNATE[®] (tranylcypromine
1024 sulfate), or MARPLAN^{®*} (isocarboxazid).
- 1025 • have or had an eating disorder such as anorexia nervosa or bulimia.
- 1026 • are allergic to the active ingredient in ZYBAN, bupropion, or to any of the inactive
1027 ingredients. See the end of this leaflet for a complete list of ingredients in ZYBAN.

1028 **Can I take ZYBAN if I have mild-to-moderate chronic bronchitis and/or emphysema (also 1029 called chronic obstructive pulmonary disease or COPD)?**

1030 Yes, ZYBAN combined with a behavior modification program has been shown to help people
1031 with COPD quit smoking. It is important to participate in the behavior program, counseling, or
1032 other support program your health care professional recommends.

1033 **What should I tell my doctor before using ZYBAN?**

- 1034 • **Tell your doctor about your medical conditions.** Tell your doctor if you:

- 1039 • **are pregnant or plan to become pregnant.** It is not known if ZYBAN can harm your
1040 unborn baby. If you can use ZYBAN while you are pregnant, talk to your doctor about
1041 how you can be on the Bupropion Pregnancy Registry.
- 1042 • **are breastfeeding.** ZYBAN passes through your milk. It is not known if ZYBAN can
1043 harm your baby.
- 1044 • **have liver problems,** especially cirrhosis of the liver.
- 1045 • have kidney problems.
- 1046 • have an eating disorder such as anorexia nervosa or bulimia.
- 1047 • have had a head injury.
- 1048 • have had a seizure (convulsion, fit).
- 1049 • have a tumor in your nervous system (brain or spine).
- 1050 • have had a heart attack, heart problems, or high blood pressure.
- 1051 • are a diabetic taking insulin or other medicines to control your blood sugar.
- 1052 • drink a lot of alcohol.
- 1053 • abuse prescription medicines or street drugs.
- 1054
- 1055 • **Tell your doctor about all the medicines you take,** including prescription and non-
1056 prescription medicines, vitamins, and herbal supplements. Many medicines increase your
1057 chances of getting seizures or other serious side effects if you take them while you are using
1058 ZYBAN.

1059 **How should I take ZYBAN?**

- 1061 • Take ZYBAN exactly as prescribed by your doctor.
- 1062 • **Do not chew, cut, or crush ZYBAN Tablets.** You must swallow the tablets whole. **Tell**
1063 **your doctor if you cannot swallow medicine tablets.**
- 1064 • Take ZYBAN at the same time each day.
- 1065 • Take your doses of ZYBAN at least 8 hours apart.
- 1066 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and
1067 take your next tablet at the regular time. **This is very important.** Too much ZYBAN can
1068 increase your chance of having a seizure.
- 1069 • If you take too much ZYBAN, or overdose, call your local emergency room or poison
1070 control center right away.
- 1071 • **Do not take any other medicines while using ZYBAN unless your doctor has told you it**
1072 **is okay.**
- 1073 • Do not change your dose or stop taking ZYBAN without talking with your doctor first.
- 1074

1075 **How long should I take ZYBAN?**

1076 Most people should take ZYBAN for at least 7 to 12 weeks. Some people may need to take
1077 ZYBAN for a longer period of time to assist in their smoking cessation efforts. Follow your
1078 doctor's instructions.

1079

1080 When should I stop smoking?

1081 It takes about 1 week for ZYBAN to reach the right levels in your body to be effective. So, to
1082 maximize your chance of quitting, you should not stop smoking until you have been taking
1083 ZYBAN for 1 week. You should set a date to stop smoking during the second week you're
1084 taking ZYBAN.

1085

1086 Can I smoke while taking ZYBAN?

1087 It is not physically dangerous to smoke and use ZYBAN at the same time. However, continuing
1088 to smoke after the date you set to stop smoking will seriously reduce your chance of breaking
1089 your smoking habit.

1090

1091 Can ZYBAN be used at the same time as nicotine patches?

1092 Yes, ZYBAN and nicotine patches can be used at the same time but should only be used together
1093 under the supervision of your doctor. Using ZYBAN and nicotine patches together may raise
1094 your blood pressure, sometimes severely. Tell your doctor if you are planning to use nicotine
1095 replacement therapy because your doctor will probably want to check your blood pressure
1096 regularly to make sure that it stays within acceptable levels.

1097

1098 **DO NOT SMOKE AT ANY TIME** if you are using a nicotine patch or any other nicotine
1099 product along with ZYBAN. It is possible to get too much nicotine and have serious side effects.

1100

1101 What should I avoid while taking ZYBAN?

- 1102 • Do not drink a lot of alcohol while taking ZYBAN. If you usually drink a lot of alcohol, talk
1103 with your doctor before suddenly stopping. If you suddenly stop drinking alcohol, you may
1104 increase your chance of having seizures.
- 1105 • Do not drive a car or use heavy machinery until you know how ZYBAN affects you.
1106 ZYBAN can impair your ability to perform these tasks.

1107

1108 What are possible side effects of ZYBAN?

- 1109 • **Seizures.** Some patients get seizures while taking ZYBAN. **If you have a seizure while**
1110 **taking ZYBAN, stop taking the tablets and call your doctor right away.** Do not take
1111 ZYBAN again if you have a seizure.
- 1112 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes
1113 severe, while taking ZYBAN. The chance of high blood pressure may be increased if you
1114 also use nicotine replacement therapy (for example, a nicotine patch) to help you stop
1115 smoking (see "Can ZYBAN be used at the same time as nicotine patches?").
- 1116 • **Severe allergic reactions: Stop taking ZYBAN and call your doctor right away** if you get
1117 a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or around the
1118 eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be
1119 signs of a serious allergic reaction.
- 1120 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while
1121 taking ZYBAN, including delusions (believe you are someone else), hallucinations (seeing or

1122 hearing things that are not there), paranoia (feeling that people are against you), or feeling
1123 confused. If this happens to you, call your doctor.

1124
1125 The most common side effects of ZYBAN are dry mouth and difficulty sleeping. These side
1126 effects are generally mild and often disappear after a few weeks. If you have difficulty sleeping,
1127 do not take your medicine too close to bedtime.

1128
1129 Tell your doctor right away about any side effects that bother you.

1130
1131 These are not all the side effects of ZYBAN. For a complete list, ask your doctor or pharmacist.

1132

1133 **How should I store ZYBAN?**

- 1134 • Store ZYBAN at room temperature. Store out of direct sunlight. Keep ZYBAN in its tightly
1135 closed bottle.
- 1136 • ZYBAN may have an odor.

1137

1138 **General Information about ZYBAN.**

- 1139 • Medicines are sometimes prescribed for purposes other than those listed in a Medication
1140 Guide. Do not use ZYBAN for a condition for which it was not prescribed. Do not give
1141 ZYBAN to other people, even if they have the same symptoms you have. It may harm them.
1142 Keep ZYBAN out of the reach of children.

1143

1144 This Medication Guide summarizes important information about ZYBAN. For more information,
1145 talk with your doctor. You can ask your doctor or pharmacist for information about ZYBAN that
1146 is written for health professionals.

1147

1148 **What are the ingredients in ZYBAN?**

1149 Active ingredient: bupropion hydrochloride.

1150

1151 Inactive ingredients: carnauba wax, cysteine hydrochloride, hypromellose, magnesium stearate,
1152 microcrystalline cellulose, polyethylene glycol, polysorbate 80 and titanium dioxide. The tablets
1153 are printed with edible black ink. In addition, the 150-mg tablet contains FD&C Blue No. 2 Lake
1154 and FD&C Red No. 40 Lake.

1155

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1159 Pharmaceutical Services, Inc.

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1161 **R_x only**

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1163 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**

1164

1165 September 2006

MG-ZY:2

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1167
1168 Distributed by:
1169 GlaxoSmithKline
1170 Research Triangle Park, NC 27709

1171
1172 Manufactured by:
1173 GlaxoSmithKline
1174 Research Triangle Park
1175 or
1176 DSM Pharmaceuticals, Inc.
1177 Greenville, NC 27834

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1180
1181 September 2006

RL-2294

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