

842 dosing should be considered in patients with mild to moderate hepatic cirrhosis (see CLINICAL  
843 PHARMACOLOGY, WARNINGS, and PRECAUTIONS).

844 **Dosage Adjustment for Patients with Impaired Renal Function:** ZYBAN should be  
845 used with caution in patients with renal impairment and a reduced frequency of dosing should be  
846 considered (see CLINICAL PHARMACOLOGY and PRECAUTIONS).

## 847 HOW SUPPLIED

848 ZYBAN Sustained-Release Tablets, 150 mg of bupropion hydrochloride, are purple, round,  
849 biconvex, film-coated tablets printed with “ZYBAN 150” in bottles of 60 (NDC 0173-0556-02)  
850 tablets and the ZYBAN Advantage Pack<sup>®</sup> containing 1 bottle of 60 (NDC 0173-0556-01) tablets.

851 **Store at controlled room temperature, 20° to 25°C (68° to 77°F) (see USP). Dispense in**  
852 **tight, light-resistant containers as defined in the USP.**

853

## 854 MEDICATION GUIDE

### 855 ZYBAN<sup>®</sup> (zi ban)

### 856 (bupropion hydrochloride) Sustained-Release Tablets

857

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

862

863 **IMPORTANT: Be sure to read both sections of this Medication Guide. The first section is**  
864 **about the risk of suicidal thoughts and actions with antidepressant medicines; the second**  
865 **section is entitled “What other important information should I know about ZYBAN?”**

866

### 867 Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and 868 Suicidal Thoughts or Actions

869

870 Although ZYBAN is not a treatment for depression, it contains the same active ingredient as the  
871 antidepressant medications WELLBUTRIN<sup>®</sup>, WELLBUTRIN SR<sup>®</sup>, and WELLBUTRIN XL<sup>®</sup>.  
872 This section of the Medication Guide is only about the risk of suicidal thoughts and actions with  
873 antidepressant medicines. **Talk to your, or your family member’s, healthcare provider**  
874 **about:**

- 875 • all risks and benefits of treatment with antidepressant medicines
- 876 • all treatment choices for depression or other serious mental illness

877

878 **What is the most important information I should know about antidepressant medicines,**  
879 **depression and other serious mental illnesses, and suicidal thoughts or actions?**

- 880 1. **Antidepressant medicines may increase suicidal thoughts or actions in some children,**  
881 **teenagers, and young adults within the first few months of treatment.**
- 882 2. **Depression and other serious mental illnesses are the most important causes of suicidal**  
883 **thoughts and actions. Some people may have a particularly high risk of having suicidal**  
884 **thoughts or actions.** These include people who have (or have a family history of) bipolar  
885 illness (also called manic-depressive illness) or suicidal thoughts or actions.
- 886 3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a**  
887 **family member?**
- 888 • Pay close attention to any changes, especially sudden changes, in mood, behaviors,  
889 thoughts, or feelings. This is very important when an antidepressant medicine is started or  
890 when the dose is changed.
  - 891 • Call the healthcare provider right away to report new or sudden changes in mood,  
892 behavior, thoughts, or feelings.
  - 893 • Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare  
894 provider between visits as needed, especially if you have concerns about symptoms.

895  
896 **Call a healthcare provider right away if you or your family member has any of the**  
897 **following symptoms, especially if they are new, worse, or worry you:**

- 898
- thoughts about suicide or dying
  - attempts to commit suicide
  - new or worse depression
  - new or worse anxiety
  - feeling very agitated or restless
  - panic attacks
  - trouble sleeping (insomnia)
  - new or worse irritability
  - acting aggressive, being angry, or violent
  - acting on dangerous impulses
  - an extreme increase in activity and talking (mania)
  - other unusual changes in behavior or mood

899

900 **What else do I need to know about antidepressant medicines?**

- 901 • **Never stop an antidepressant medicine without first talking to a healthcare provider.**  
902 Stopping an antidepressant medicine suddenly can cause other symptoms.
- 903 • **Antidepressants are medicines used to treat depression and other illnesses.** It is  
904 important to discuss all the risks of treating depression and also the risks of not treating it.  
905 Patients and their families or other caregivers should discuss all treatment choices with the  
906 healthcare provider, not just the use of antidepressants.
- 907 • **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the  
908 side effects of the medicine prescribed for you or your family member.
- 909 • **Antidepressant medicines can interact with other medicines.** Know all of the medicines  
910 that you or your family member takes. Keep a list of all medicines to show the healthcare  
911 provider. Do not start new medicines without first checking with your healthcare provider.

- 912 • **Not all antidepressant medicines prescribed for children are FDA approved for use in**  
913 **children.** Talk to your child’s healthcare provider for more information.

914  
915 ZYBAN has not been studied in children under the age of 18 and is not approved for use in  
916 children and teenagers.

### 917 **What other important information should I know about ZYBAN?**

918  
919  
920 **There is a chance of having a seizure (convulsion, fit) with ZYBAN, especially in people:**

- 921 • with certain medical problems.  
922 • who take certain medicines.

923  
924 The chance of having seizures increases with higher doses of ZYBAN. For more information,  
925 see the sections “Who should not take ZYBAN?” and “What should I tell my doctor before using  
926 ZYBAN?” Tell your doctor about all of your medical conditions and all the medicines you take.  
927 **Do not take any other medicines while you are using ZYBAN unless your doctor has said it**  
928 **is okay to take them.**

929  
930 **If you have a seizure while taking ZYBAN, stop taking the tablets and call your doctor**  
931 **right away.** Do not take ZYBAN again if you have a seizure.

### 932 **What is ZYBAN?**

933  
934 ZYBAN is a prescription medicine to help people quit smoking. Studies have shown that more  
935 than one third of people quit smoking for at least 1 month while taking ZYBAN and participating  
936 in a patient support program. For many patients, ZYBAN reduces withdrawal symptoms and the  
937 urge to smoke. ZYBAN should be used with a patient support program. It is important to  
938 participate in the behavioral program, counseling, or other support program your health care  
939 professional recommends.

### 940 **Who should not take ZYBAN?**

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

- 942  
943 • have or had a seizure disorder or epilepsy.  
944 • **are taking WELLBUTRIN, WELLBUTRIN SR, WELLBUTRIN XL, or any other**  
945 **medicines that contain bupropion hydrochloride.** Bupropion is the same active ingredient  
946 that is in ZYBAN.  
947 • drink a lot of alcohol and abruptly stop drinking, or use medicines called sedatives (these  
948 make you sleepy) or benzodiazepines and you stop using them all of a sudden.  
949 • have taken within the last 14 days medicine for depression called a monoamine oxidase  
950 inhibitor (MAOI), such as NARDIL<sup>®\*</sup> (phenelzine sulfate), PARNATE<sup>®</sup> (tranylcypromine  
951 sulfate), or MARPLAN<sup>®\*</sup> (isocarboxazid).  
952 • have or had an eating disorder such as anorexia nervosa or bulimia.

- 953 • are allergic to the active ingredient in ZYBAN, bupropion, or to any of the inactive  
954 ingredients. See the end of this leaflet for a complete list of ingredients in ZYBAN.  
955

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

958 Yes, ZYBAN combined with a behavior modification program has been shown to help people  
959 with COPD quit smoking. It is important to participate in the behavior program, counseling, or  
960 other support program your health care professional recommends.  
961

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

- 963 • **Tell your doctor about your medical conditions.** Tell your doctor if you:
- 964 • **are pregnant or plan to become pregnant.** It is not known if ZYBAN can harm your  
965 unborn baby. If you can use ZYBAN while you are pregnant, talk to your doctor about  
966 how you can be on the Bupropion Pregnancy Registry.
  - 967 • **are breastfeeding.** ZYBAN passes through your milk. It is not known if ZYBAN can  
968 harm your baby.
  - 969 • **have liver problems,** especially cirrhosis of the liver.
  - 970 • have kidney problems.
  - 971 • have an eating disorder such as anorexia nervosa or bulimia.
  - 972 • have had a head injury.
  - 973 • have had a seizure (convulsion, fit).
  - 974 • have a tumor in your nervous system (brain or spine).
  - 975 • have had a heart attack, heart problems, or high blood pressure.
  - 976 • are a diabetic taking insulin or other medicines to control your blood sugar.
  - 977 • drink a lot of alcohol.
  - 978 • abuse prescription medicines or street drugs.
- 979 • **Tell your doctor about all the medicines you take,** including prescription and non-  
980 prescription medicines, vitamins, and herbal supplements. Many medicines increase your  
981 chances of getting seizures or other serious side effects if you take them while you are using  
982 ZYBAN.  
983

984 **How should I take ZYBAN?**

- 985 • Take ZYBAN exactly as prescribed by your doctor.
- 986 • **Do not chew, cut, or crush ZYBAN Tablets.** You must swallow the tablets whole. **Tell**  
987 **your doctor if you cannot swallow medicine tablets.**
- 988 • Take ZYBAN at the same time each day.
- 989 • Take your doses of ZYBAN at least 8 hours apart.
- 990 • If you miss a dose, do not take an extra tablet to make up for the dose you forgot. Wait and  
991 take your next tablet at the regular time. **This is very important.** Too much ZYBAN can  
992 increase your chance of having a seizure.

- 993 • If you take too much ZYBAN, or overdose, call your local emergency room or poison  
994 control center right away.
- 995 • **Do not take any other medicines while using ZYBAN unless your doctor has told you it**  
996 **is okay.**
- 997 • Do not change your dose or stop taking ZYBAN without talking with your doctor first.  
998

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

1000 Most people should take ZYBAN for at least 7 to 12 weeks. Some people may need to take  
1001 ZYBAN for a longer period of time to assist in their smoking cessation efforts. Follow your  
1002 doctor's instructions.

1003

1004 **When should I stop smoking?**

1005 It takes about 1 week for ZYBAN to reach the right levels in your body to be effective. So, to  
1006 maximize your chance of quitting, you should not stop smoking until you have been taking  
1007 ZYBAN for 1 week. You should set a date to stop smoking during the second week you're  
1008 taking ZYBAN.

1009

1010 **Can I smoke while taking ZYBAN?**

1011 It is not physically dangerous to smoke and use ZYBAN at the same time. However, continuing  
1012 to smoke after the date you set to stop smoking will seriously reduce your chance of breaking  
1013 your smoking habit.

1014

1015 **Can ZYBAN be used at the same time as nicotine patches?**

1016 Yes, ZYBAN and nicotine patches can be used at the same time but should only be used together  
1017 under the supervision of your doctor. Using ZYBAN and nicotine patches together may raise  
1018 your blood pressure, sometimes severely. Tell your doctor if you are planning to use nicotine  
1019 replacement therapy because your doctor will probably want to check your blood pressure  
1020 regularly to make sure that it stays within acceptable levels.

1021

1022 **DO NOT SMOKE AT ANY TIME** if you are using a nicotine patch or any other nicotine  
1023 product along with ZYBAN. It is possible to get too much nicotine and have serious side effects.

1024

1025 **What should I avoid while taking ZYBAN?**

- 1026 • Do not drink a lot of alcohol while taking ZYBAN. If you usually drink a lot of alcohol, talk  
1027 with your doctor before suddenly stopping. If you suddenly stop drinking alcohol, you may  
1028 increase your chance of having seizures.
- 1029 • Do not drive a car or use heavy machinery until you know how ZYBAN affects you.  
1030 ZYBAN can impair your ability to perform these tasks.

1031

1032 **What are possible side effects of ZYBAN?**

- 1033 • **Seizures.** Some patients get seizures while taking ZYBAN. **If you have a seizure while**  
1034 **taking ZYBAN, stop taking the tablets and call your doctor right away.** Do not take  
1035 ZYBAN again if you have a seizure.
- 1036 • **Hypertension (high blood pressure).** Some patients get high blood pressure, sometimes  
1037 severe, while taking ZYBAN. The chance of high blood pressure may be increased if you  
1038 also use nicotine replacement therapy (for example, a nicotine patch) to help you stop  
1039 smoking (see “Can ZYBAN be used at the same time as nicotine patches?”).
- 1040 • **Severe allergic reactions: Stop taking ZYBAN and call your doctor right away** if you get  
1041 a rash, itching, hives, fever, swollen lymph glands, painful sores in the mouth or around the  
1042 eyes, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be  
1043 signs of a serious allergic reaction.
- 1044 • **Unusual thoughts or behaviors.** Some patients have unusual thoughts or behaviors while  
1045 taking ZYBAN, including delusions (believe you are someone else), hallucinations (seeing or  
1046 hearing things that are not there), paranoia (feeling that people are against you), or feeling  
1047 confused. If this happens to you, call your doctor.

1048  
1049 The most common side effects of ZYBAN are dry mouth and difficulty sleeping. These side  
1050 effects are generally mild and often disappear after a few weeks. If you have difficulty sleeping,  
1051 do not take your medicine too close to bedtime.

1052  
1053 Tell your doctor right away about any side effects that bother you.

1054  
1055 These are not all the side effects of ZYBAN. For a complete list, ask your doctor or pharmacist.

### 1056 1057 **How should I store ZYBAN?**

- 1058 • Store ZYBAN at room temperature. Store out of direct sunlight. Keep ZYBAN in its tightly  
1059 closed bottle.
- 1060 • ZYBAN may have an odor.

### 1061 1062 **General Information about ZYBAN.**

- 1063 • Medicines are sometimes prescribed for purposes other than those listed in a Medication  
1064 Guide. Do not use ZYBAN for a condition for which it was not prescribed. Do not give  
1065 ZYBAN to other people, even if they have the same symptoms you have. It may harm them.  
1066 Keep ZYBAN out of the reach of children.

1067  
1068 This Medication Guide summarizes important information about ZYBAN. For more information,  
1069 talk with your doctor. You can ask your doctor or pharmacist for information about ZYBAN that  
1070 is written for health professionals.

### 1071 1072 **What are the ingredients in ZYBAN?**

1073 Active ingredient: bupropion hydrochloride.

1074

1075 Inactive ingredients: carnauba wax, cysteine hydrochloride, hypromellose, magnesium stearate,  
1076 microcrystalline cellulose, polyethylene glycol, polysorbate 80 and titanium dioxide. The tablets  
1077 are printed with edible black ink. In addition, the 150-mg tablet contains FD&C Blue No. 2 Lake  
1078 and FD&C Red No. 40 Lake.

1079

1080 \*The following are registered trademarks of their respective manufacturers: NARDIL<sup>®</sup>/Warner  
1081 Lambert Company; MARPLAN<sup>®</sup>/Oxford Pharmaceutical Services, Inc.

1082

1083 **R<sub>x</sub> only**

1084

1085 This Medication Guide has been approved by the U.S. Food and Drug Administration.

1086

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1088



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