

912 Treatment of Exercise-Induced Bronchospasm: Patients using SEREVENT DISKUS
913 for the treatment of EIB should not use additional doses for 12 hours. Patients who are receiving
914 SEREVENT DISKUS twice daily should not use additional SEREVENT for prevention of EIB.

915
916 SEREVENT and DISKUS are registered trademarks of the GSK group of companies.

917
918



919
920 GlaxoSmithKline
921 Research Triangle Park, NC 27709

922
923 ©2014, the GSK group of companies. All rights reserved.

924
925 SRD:xPI

926
927
928

MEDICATION GUIDE

929 **SEREVENT® DISKUS® [ser' uh-vent disk' us]**
930 **(salmeterol xinafoate inhalation powder)**

931
932 Read the Medication Guide that comes with SEREVENT DISKUS before you start
933 using it and each time you get a refill. There may be new information. This
934 Medication Guide does not take the place of talking to your healthcare provider
935 about your medical condition or treatment.

936
937 **What is the most important information I should know about SEREVENT**
938 **DISKUS?**

939 **SEREVENT DISKUS can cause serious side effects, including:**

- 940 • **People with asthma who take long-acting beta₂-adrenergic agonist**
941 **(LABA) medicines, such as salmeterol xinafoate (the medicine in**
942 **SEREVENT DISKUS), have an increased risk of death from asthma**
943 **problems.**
- 944 • **It is not known if LABA medicines such as salmeterol xinafoate increase**
945 **the risk of death in people with COPD.**
- 946 • **Call your healthcare provider if breathing problems worsen over time**
947 **while using SEREVENT DISKUS. You may need different treatment.**

- 948 • **Get emergency medical care if:**
949 • your breathing problems worsen quickly.
950 • you use your rescue inhaler, but it does not relieve your breathing problems.
- 951 • **Do not use SEREVENT DISKUS as your only asthma medicine. SEREVENT**
952 **DISKUS must only be used with a long-term asthma control medicine,**
953 **such as an inhaled corticosteroid.**
- 954 • SEREVENT DISKUS should be used only if your healthcare provider decides that
955 your asthma is not well controlled with a long-term asthma control medicine,
956 such as an inhaled corticosteroid. When your asthma is well controlled, your
957 healthcare provider may tell you to stop taking SEREVENT DISKUS. Your
958 healthcare provider will decide if you can stop SEREVENT DISKUS without loss of
959 asthma control. You will continue taking your long-term asthma control
960 medicine, such as an inhaled corticosteroid.
- 961 • Children and adolescents who take LABA medicines may have an increased risk
962 of being hospitalized for asthma problems.
963

964 **What is SEREVENT DISKUS?**

- 965 • SEREVENT DISKUS is a prescription inhaled LABA medicine. LABA medicines
966 such as salmeterol xinafoate help the muscles around the airways in your lungs
967 stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness,
968 and shortness of breath. These symptoms can happen when the muscles around
969 the airways tighten. This makes it hard to breathe.
- 970 • SEREVENT DISKUS is not used to relieve sudden breathing problems.
- 971 • It is not known if SEREVENT DISKUS is safe and effective in children younger
972 than 4 years.
- 973 • SEREVENT DISKUS is used for asthma, exercise-induced bronchospasm (EIB),
974 and chronic obstructive pulmonary disease (COPD) as follows:

975 **Asthma:**

976 SEREVENT DISKUS is a prescription medicine used to control symptoms of
977 asthma and to prevent symptoms such as wheezing in adults and children aged
978 4 years and older.

979 SEREVENT DISKUS contains salmeterol xinafoate. LABA medicines such as
980 salmeterol xinafoate increase the risk of death from asthma problems.

981 SEREVENT DISKUS is not for adults and children with asthma who are well
982 controlled with an asthma control medicine, such as a low to medium dose of an
983 inhaled corticosteroid medicine.

984 **Exercise-Induced Bronchospasm (EIB):**

985 SEREVENT DISKUS is used to prevent wheezing caused by exercise in adults and
986 children aged 4 years and older.

- 987 • If you only have EIB, your healthcare provider may only prescribe SEREVENT
988 DISKUS for your condition.
- 989 • If you have EIB and asthma, your healthcare provider should also prescribe
990 an asthma control medicine, such as an inhaled corticosteroid.

991 **Chronic Obstructive Pulmonary Disease (COPD):**

992 COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or
993 both.

994 SEREVENT DISKUS is a prescription medicine used long term as 1 inhalation 2
995 times each day to improve symptoms of COPD for better breathing.

996

997 **Who should not use SEREVENT DISKUS?**

998 Do not use SEREVENT DISKUS:

- 999 • to treat your asthma without a long-term asthma control medicine, such as an
1000 inhaled corticosteroid.
- 1001 • if you have a severe allergy to milk proteins. Ask your healthcare provider if you
1002 are not sure.
- 1003 • if you are allergic to salmeterol xinafoate or any of the ingredients in SEREVENT
1004 DISKUS. See “What are the ingredients in SEREVENT DISKUS?” below for a
1005 complete list of ingredients.

1006

1007 **What should I tell my healthcare provider before using SEREVENT DISKUS?**

1008 **Tell your healthcare provider about all of your health conditions, including**
1009 **if you:**

- 1010 • have heart problems.
- 1011 • have high blood pressure.
- 1012 • have seizures.
- 1013 • have thyroid problems.
- 1014 • have diabetes.
- 1015 • have liver problems.

- 1016 • are allergic to any of the ingredients in SEREVENT DISKUS, any other medicines,
1017 or food products. See “What are the ingredients in SEREVENT DISKUS?” below
1018 for a complete list of ingredients.
- 1019 • have any other medical conditions.
- 1020 • are pregnant or planning to become pregnant. It is not known if SEREVENT
1021 DISKUS may harm your unborn baby.
- 1022 • are breastfeeding. It is not known if the medicine in SEREVENT DISKUS passes
1023 into your milk and if it can harm your baby

1024 **Tell your healthcare provider about all the medicines you take**, including
1025 prescription and over-the-counter medicines, vitamins, and herbal supplements.
1026 SEREVENT DISKUS and certain other medicines may interact with each other. This
1027 may cause serious side effects. Especially, tell your healthcare provider if you take
1028 antifungal or anti-HIV medicines.

1029 Know the medicines you take. Keep a list of them to show your healthcare provider
1030 and pharmacist when you get a new medicine.

1031

1032 **How should I use SEREVENT DISKUS?**

1033 **Read the step-by-step instructions for using SEREVENT DISKUS at the end**
1034 **of this Medication Guide.**

- 1035 • **Do not** use SEREVENT DISKUS unless your healthcare provider has taught you
1036 how to use the inhaler and you understand how to use it correctly.
- 1037 • Children should use SEREVENT DISKUS with an adult’s help, as instructed by the
1038 child’s healthcare provider.
- 1039 • Use SEREVENT DISKUS exactly as prescribed. **Do not** use SEREVENT DISKUS
1040 more often than prescribed.
- 1041 • **For asthma and COPD**, the usual dose is 1 inhalation of SEREVENT DISKUS
1042 2 times each day. Use SEREVENT DISKUS at the same time each day, about 12
1043 hours apart.
- 1044 • **For preventing exercise-induced bronchospasm**, the usual dose is
1045 1 inhalation at least 30 minutes before exercise. Do not use SEREVENT DISKUS
1046 more often than every 12 hours. Do not use extra SEREVENT DISKUS before
1047 exercise if you already use it 2 times each day.
- 1048 • If you miss a dose of SEREVENT DISKUS, just skip that dose. Take your next
1049 dose at your usual time. Do not take 2 doses at 1 time.

- 1050 • If you take too much SEREVENT DISKUS, call your healthcare provider or go to
1051 the nearest hospital emergency room right away if you have any unusual
1052 symptoms, such as worsening shortness of breath, chest pain, increased heart
1053 rate, or shakiness.
- 1054 • **Do not use other medicines that contain a LABA for any reason.** Ask your
1055 healthcare provider or pharmacist if any of your other medicines are LABA
1056 medicines.
- 1057 • Do not stop using SEREVENT DISKUS unless told to do so by your healthcare
1058 provider because your symptoms might get worse. Your healthcare provider will
1059 change your medicines as needed.
- 1060 • **SEREVENT DISKUS does not relieve sudden symptoms.** Always have a
1061 rescue inhaler with you to treat sudden symptoms. If you do not have a rescue
1062 inhaler, call your healthcare provider to have one prescribed for you.
- 1063 • Call your healthcare provider or get medical care right away if:
- 1064 • your breathing problems get worse.
 - 1065 • you need to use your rescue inhaler more often than usual.
 - 1066 • your rescue inhaler does not work as well to relieve your symptoms.
 - 1067 • you need to use 4 or more inhalations of your rescue inhaler in 24 hours for
1068 2 or more days in a row.
 - 1069 • you use 1 whole canister of your rescue inhaler in 8 weeks.
 - 1070 • your peak flow meter results decrease. Your healthcare provider will tell you
1071 the numbers that are right for you.
 - 1072 • you have asthma and your symptoms do not improve after using SEREVENT
1073 DISKUS regularly for 1 week.
- 1074

1075 **What are the possible side effects with SEREVENT DISKUS?**

1076 **SEREVENT DISKUS can cause serious side effects, including:**

- 1077 • **See “What is the most important information I should know about**
1078 **SEREVENT DISKUS?”**
- 1079 • **sudden breathing problems immediately after inhaling your medicine**
- 1080 • **effects on heart**
 - 1081 • increased blood pressure
 - 1082 • a fast or irregular heartbeat
 - 1083 • chest pain
- 1084 • **effects on nervous system**
 - 1085 • tremor
 - 1086 • nervousness

- 1087 • **serious allergic reactions.** Call your healthcare provider or get emergency
1088 medical care if you get any of the following symptoms of a serious allergic
1089 reaction:
1090 • rash
1091 • hives
1092 • swelling of your face, mouth, and tongue
1093 • breathing problems.

- 1094 • **changes in laboratory blood values (sugar, potassium)**

1095 **Common side effects of SEREVENT DISKUS include:**

1096 **Asthma:**

- 1097 • headache
1098 • nasal congestion
1099 • bronchitis
1100 • throat irritation
1101 • runny nose
1102 • flu

1103 **COPD:**

- 1104 • headache
1105 • musculoskeletal pain
1106 • throat irritation
1107 • cough
1108 • respiratory infection

1109 Tell your healthcare provider about any side effect that bothers you or that does
1110 not go away.

1111 These are not all the side effects with SEREVENT DISKUS. Ask your healthcare
1112 provider or pharmacist for more information.

1113 Call your doctor for medical advice about side effects. You may report side effects
1114 to FDA at 1-800-FDA-1088.

1115

1116 **How should I store SEREVENT DISKUS?**

- 1117 • Store SEREVENT DISKUS at room temperature between 68°F and 77°F (20°C
1118 and 25°C). Keep in a dry place away from heat and sunlight.
1119 • Store SEREVENT DISKUS in the unopened foil pouch and only open when ready
1120 for use.
1121 • Safely throw away SEREVENT DISKUS in the trash 6 weeks after you open the
1122 foil pouch or when the counter reads 0, whichever comes first.

- **Keep SEREVENT DISKUS and all medicines out of the reach of children.**

1124

1125 **General information about SEREVENT DISKUS**

1126 Medicines are sometimes prescribed for purposes not mentioned in a Medication
1127 Guide. Do not use SEREVENT DISKUS for a condition for which it was not
1128 prescribed. Do not give your SEREVENT DISKUS to other people, even if they have
1129 the same condition that you have. It may harm them.

1130 This Medication Guide summarizes the most important information about SEREVENT
1131 DISKUS. If you would like more information, talk with your healthcare provider or
1132 pharmacist. You can ask your healthcare provider or pharmacist for information
1133 about SEREVENT DISKUS that was written for healthcare professionals.

1134 For more information about SEREVENT DISKUS, call 1-888-825-5249 or visit our
1135 website at www.serevent.com.

1136

1137 **What are the ingredients in SEREVENT DISKUS?**

1138 Active ingredient: salmeterol xinafoate

1139 Inactive ingredient: lactose monohydrate (contains milk proteins)

1140

1141 **Instructions for Use**

1142 **For Oral Inhalation Only**

1143

1144 **Your SEREVENT DISKUS inhaler**

1145



1146 **Figure A**

1147

1148 **Read this information before you start using your SEREVENT DISKUS** 1149 **inhaler:**

- Take SEREVENT DISKUS out of the foil pouch just before you use it for the first
1152 time. Safely throw away the pouch. The DISKUS will be in the closed position.

1153 • Write the date you opened the foil pouch in the first blank line on the label. **See**
1154 **Figure A.**

1155 • Write the “use by” date in the second blank line on the label. **See Figure A.**
1156 That date is 6 weeks after the date you wrote in the first line.

1157 • The counter should read **60**. If you have an institutional pack (with
1158 “INSTITUTIONAL PACK” on the foil pouch), the counter should read **28**.

1159

1160 **How to use your SEREVENT DISKUS inhaler**

1161 **Follow these steps every time you use SEREVENT DISKUS.**

1162 **Step 1. Open your SEREVENT DISKUS.**

1163 • Hold the DISKUS in your left hand and place the thumb of your right hand in the
1164 thumb grip. Push the thumb grip away from you as far as it will go until the
1165 mouthpiece shows and snaps into place. **See Figure B.**

1166 **Step 2. Slide the lever until you hear it click.**

1167 • **Hold the DISKUS in a level, flat position** with the mouthpiece towards you.
1168 Slide the lever away from the mouthpiece as far as it will go until it **clicks**. **See**
1169 **Figure C.**

1170 • The number on the counter will count down by 1. The DISKUS is now ready to
1171 use.



1172 **Figure B**



1173 **Figure C**

1174

1175 Follow the instructions below so you will not accidentally waste a dose:

- 1176 • **Do not** close the DISKUS.
- 1177 • **Do not** tilt the DISKUS.
- 1178 • **Do not** move the lever on the DISKUS.

1179 **Step 3. Inhale your medicine.**

1180 • Before you breathe in your dose from the DISKUS, breathe out (exhale) as long
1181 as you can while you hold the DISKUS level and away from your mouth. **See**

1182 **Figure D.** Do not breathe into the mouthpiece.

- 1183 • Put the mouthpiece to your lips. **See Figure E.** Breathe in quickly and deeply
1184 through the DISKUS. Do not breathe in through your nose.



1185
1186 **Figure D**



1187
1188 **Figure E**

- 1188 • Remove the DISKUS from your mouth **and hold your breath for about**
1189 **10 seconds**, or for as long as is comfortable for you.
- 1190 • **Breathe out slowly as long as you can. See Figure D.**
- 1191 • The DISKUS delivers your dose of medicine as a very fine powder that you may
1192 or may not taste or feel. **Do not** take an extra dose from the DISKUS even if
1193 you do not taste or feel the medicine.

1194 **Step 4. Close the DISKUS.**

- 1195 • Place your thumb in the thumb grip and slide it back towards you as far as it will
1196 go. **See Figure F.** Make sure the DISKUS clicks shut and you cannot see the
1197 mouthpiece.
- 1198 • The DISKUS is now ready for you to take your next scheduled dose in about 12
1199 hours. **When you are ready to take your next dose, repeat Steps 1**
1200 **through 4.**



1201
1202 **Figure F**

1203
1204 **When should you get a refill?**

1205 The counter on top of the DISKUS shows you how many doses are left. After you
1206 have taken **55** doses (**23** doses from the institutional pack), the numbers **5** to **0**

1207 will show in red. **See Figure G.** These numbers warn you there are only a few
1208 doses left and are a reminder to get a refill.
1209



1210
1211 **Figure G**
1212

1213 **For correct use of the DISKUS, remember:**

- 1214 • Always use the DISKUS in a level, flat position.
- 1215 • Make sure the lever firmly clicks into place.
- 1216 • Hold your breath for about 10 seconds after inhaling. Then breathe out fully.
- 1217 • **Do not** take an extra dose, even if you did not taste or feel the powder.
- 1218 • **Do not** take the DISKUS apart.
- 1219 • **Do not** wash the DISKUS.
- 1220 • Always keep the DISKUS in a dry place.
- 1221 • **Do not** use the DISKUS with a spacer device.

1222
1223 If you have questions about SEREVENT DISKUS or how to use your inhaler, call
1224 GlaxoSmithKline (GSK) at 1-888-825-5249 or visit www.serevent.com.

1225
1226 **This Medication Guide and Instructions for Use have been approved by the**
1227 **U.S. Food and Drug Administration.**

1228
1229 SEREVENT and DISKUS are registered trademarks of the GSK group of companies.
1230
1231



1232
1233 GlaxoSmithKline
1234 Research Triangle Park, NC 27709
1235

1236 ©2014, the GSK group of companies. All rights reserved.
1237

1238 April 2014
1239 SRD: xMG

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BADRUL A CHOWDHURY
04/14/2014