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932 Month Year

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MEDICATION GUIDE

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SEREVENT[®] [ser' uh-vent] DISKUS[®]

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(salmeterol xinafoate inhalation powder)

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940 Read the Medication Guide that comes with SEREVENT DISKUS before you start using it and

941 each time you get a refill. There may be new information. This Medication Guide does not take

942 the place of talking to your healthcare provider about your medical condition or treatment.

943

944 **What is the most important information I should know about SEREVENT DISKUS?**

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

946 **1. People with asthma who take long-acting beta₂-adrenergic agonist (LABA) medicines**
947 **such as salmeterol (SEREVENT DISKUS), have an increased risk of death from**
948 **asthma problems.**

949 • Call your healthcare provider if breathing problems worsen over time while using
950 SEREVENT DISKUS. You may need a different treatment.

951 • Get emergency medical care if:

952 • breathing problems worsen quickly, and

953 • you use your rescue inhaler medicine, but it does not relieve your breathing problems.

954 **2. Do not use SEREVENT DISKUS as your only asthma medicine. SEREVENT DISKUS**
955 **must only be used with a long-term asthma-control medicine, such as an inhaled**
956 **corticosteroid.**

957 **3. When your asthma is well controlled, your healthcare provider may tell you to stop taking**
958 **SEREVENT DISKUS. Your healthcare provider will decide if you can stop SEREVENT**
959 **DISKUS without loss of asthma control. You will continue taking your long-term asthma-**
960 **control medicine, such as an inhaled corticosteroid.**

961 4. Children and adolescents who take LABA medicines may have an increased risk of being
962 hospitalized for asthma problems.

963

964 **What is SEREVENT DISKUS?**

965 • SEREVENT DISKUS is a LABA medicine. LABA medicines help the muscles around the
966 airways in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness of
967 breath. These symptoms can happen when the muscles around the airways tighten. This
968 makes it hard to breathe. In severe cases, wheezing can stop your breathing and cause death
969 if not treated right away.

970 • SEREVENT DISKUS is used for asthma, exercise-induced bronchospasm (EIB), and chronic
971 obstructive pulmonary disease (COPD) as follows:

972 **Asthma:**

973 SEREVENT DISKUS is used in adults and children aged 4 years and older, with a long-term
974 asthma control medicine, such as an inhaled corticosteroid:

- 975 • to control symptoms of asthma, and
- 976 • to prevent symptoms such as wheezing.

977 LABA medicines, such as SEREVENT DISKUS, increase the risk of death from asthma
978 problems. SEREVENT DISKUS is not for adults and children with asthma who are well
979 controlled with a long-term asthma-control medicine, such as a low to medium dose of an
980 inhaled corticosteroid medicine.

981 **Exercise-Induced Bronchospasm:**

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

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

988 **Chronic Obstructive Pulmonary Disease:**

989 SEREVENT DISKUS is used long term, 2 times each day (morning and evening) to control
990 symptoms of COPD and prevent wheezing in adults with COPD.

991

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

993 **Do not take SEREVENT DISKUS:**

- 994 • to treat your asthma without an asthma medicine known as an inhaled corticosteroid
- 995 • if you are allergic to salmeterol or any of the ingredients in SEREVENT DISKUS. Ask your
996 healthcare provider if you are not sure. See the end of this Medication Guide for a complete

997 list of ingredients in SEREVENT DISKUS.

998

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

1000 Tell your healthcare provider about all of your health conditions, including if you:

1001 • have heart problems

1002 • have high blood pressure

1003 • have seizures

1004 • have thyroid problems

1005 • have diabetes

1006 • have liver problems

1007 • are pregnant or planning to become pregnant. It is not known if SEREVENT DISKUS may
1008 harm your unborn baby.

1009 • are breastfeeding. It is not known if SEREVENT DISKUS passes into your milk and if it can
1010 harm your baby.

1011 • are allergic to SEREVENT DISKUS, any other medicines, or food products. See the end of
1012 this Medication Guide for a complete list of ingredients in SEREVENT DISKUS.

1013 Tell your healthcare provider about all the medicines you take including prescription and non-

1014 prescription medicines, vitamins, and herbal supplements. SEREVENT DISKUS and certain

1015 other medicines, especially those used to treat infections, may interact with each other. This may

1016 cause serious side effects.

1017 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist

1018 each time you get a new medicine.

1019

1020 **How do I use SEREVENT DISKUS?**

1021 See the step-by-step instructions for using the SEREVENT DISKUS at the end of this

1022 Medication Guide. Do not use SEREVENT DISKUS unless your healthcare provider has taught

1023 you and you understand everything. Ask your healthcare provider or pharmacist if you have any

1024 questions.

1025 • Children should use SEREVENT DISKUS with an adult's help, as instructed by the child's
1026 healthcare provider.

1027 • Use SEREVENT DISKUS exactly as prescribed. Do not use SEREVENT DISKUS more
1028 often than prescribed.

1029 • For asthma and COPD, the usual dose is 1 inhalation 2 times each day (morning and
1030 evening). The 2 doses should be about 12 hours apart.

1031 • For preventing exercise-induced bronchospasm, take 1 inhalation at least 30 minutes before
1032 exercise. Do not use SEREVENT DISKUS more often than every 12 hours. Do not use extra
1033 SEREVENT DISKUS before exercise if you already use it 2 times each day.

- 1034 • If you miss a dose of SEREVENT DISKUS, just skip that dose. Take your next dose at your
1035 usual time. Do not take 2 doses at one time.
- 1036 • Do not use a spacer device with SEREVENT DISKUS.
- 1037 • Do not breathe into SEREVENT DISKUS.
- 1038 • While you are using SEREVENT DISKUS 2 times each day, do not use other medicines that
1039 contain a long-acting beta₂-agonist or LABA for any reason. Ask your healthcare provider or
1040 pharmacist for a list of these medicines.
- 1041 • Do not stop using SEREVENT DISKUS or any of your asthma medicines unless told to do
1042 so by your healthcare provider because your symptoms might get worse. Your healthcare
1043 provider will change your medicines as needed.
- 1044 • SEREVENT DISKUS does not relieve sudden symptoms. Always have a rescue inhaler
1045 medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting
1046 bronchodilator, contact your healthcare provider to have one prescribed for you.
- 1047 • Call your healthcare provider or get medical care right away if:
 - 1048 • your breathing problems worsen with SEREVENT DISKUS
 - 1049 • you need to use your rescue inhaler medicine more often than usual
 - 1050 • your rescue inhaler medicine does not work as well for you at relieving symptoms
 - 1051 • you need to use 4 or more inhalations of your rescue inhaler medicine for 2 or more days
1052 in a row
 - 1053 • you use 1 whole canister of your rescue inhaler medicine in 8 weeks' time
 - 1054 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
1055 that are right for you.
 - 1056 • you have asthma and your symptoms do not improve after using SEREVENT DISKUS
1057 regularly for 1 week.
 - 1058 • after a change in your asthma medicines you have any worsening of your asthma
1059 symptoms or an increase in the need for your rescue inhaler medicine.

1061 **What are the possible side effects with SEREVENT DISKUS?**

1062 **SEREVENT DISKUS can cause serious side effects, including:**

- 1063 • **See “What is the most important information I should know about SEREVENT**
1064 **DISKUS?”**
- 1065 • **serious allergic reactions.** Call your healthcare provider or get emergency medical care if
1066 you get any of the following symptoms of a serious allergic reaction:
 - 1067 • rash
 - 1068 • hives
 - 1069 • swelling of the face, mouth, and tongue
 - 1070 • breathing problems.

1071 • **sudden breathing problems immediately after inhaling your medicine**

1072 • **effects on heart**

1073 • increased blood pressure

1074 • a fast and irregular heartbeat

1075 • chest pain

1076 • **effects on nervous system**

1077 • tremor

1078 • nervousness

1079 • **changes in blood (sugar, potassium)**

1080

1081 **Common side effects of SEREVENT DISKUS include:**

1082 **Asthma in adults and children:**

1083 • headache

1084 • nasal congestion

1085 • bronchitis

1086 • throat irritation

1087 • runny nose

1088 • flu

1089 **Chronic obstructive pulmonary disease:**

1090 • headache

1091 • musculoskeletal pain

1092 • throat irritation

1093 • cough

1094 • respiratory infection

1095 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1096 These are not all the side effects with SEREVENT DISKUS. Ask your healthcare provider or
1097 pharmacist for more information.

1098 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-
1099 800-FDA-1088.

1100

1101 **How do I store SEREVENT DISKUS?**

1102 • Store SEREVENT DISKUS at room temperature between 68°F to 77°F (20°C to 25°C).
1103 Keep in a dry place away from heat and sunlight.

1104 • Safely discard SEREVENT DISKUS 6 weeks after you remove it from the foil pouch, or
1105 after the dose indicator reads “0”, whichever comes first.

1106 • Keep SEREVENT DISKUS and all medicines out of the reach of children.

1107

1108 **General Information about SEREVENT DISKUS**

1109 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
1110 use SEREVENT DISKUS for a condition for which it was not prescribed. Do not give your
1111 SEREVENT DISKUS to other people, even if they have the same condition that you have. It
1112 may harm them.

1113 This Medication Guide summarizes the most important information about SEREVENT
1114 DISKUS. If you would like more information, talk with your healthcare provider or pharmacist.
1115 You can ask your healthcare provider or pharmacist for information about SEREVENT DISKUS
1116 that was written for healthcare professionals. You can also contact the company that makes
1117 SEREVENT DISKUS (toll free) at 1-888-825-5249 or at www.serevent.com.

1118

1119 **What are the ingredients in SEREVENT DISKUS?**

1120 Active ingredient: salmeterol xinafoate

1121 Inactive ingredient: lactose (contains milk proteins)

1122

1123 **Instructions for Using SEREVENT DISKUS**

1124 Follow the instructions below for using your SEREVENT DISKUS. **You will breathe in**
1125 **(inhale) the medicine from the DISKUS.** If you have any questions, ask your healthcare
1126 provider or pharmacist.



1127
1128 Take the SEREVENT DISKUS out of the box and foil pouch. Write the **“Pouch opened”** and
1129 **“Use by”** dates on the label on top of the DISKUS. **The “Use by” date is 6 weeks from date of**
1130 **opening the pouch.**

1131

- The DISKUS will be in the closed position when the pouch is opened.

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- The **dose indicator** on the top of the DISKUS tells you how many doses are left. The dose indicator number will decrease each time you use the DISKUS. After you have used 55 doses from the DISKUS, the numbers 5 to 0 will appear in **red** to warn you that there are only a few doses left (*see Figure 1*).



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1140

1141

Figure 1

1142 Taking a dose from the DISKUS requires the following 3 simple steps: Open, Click, Inhale.

1143

1144 **1. OPEN**

1145 Hold the DISKUS in one hand and put the thumb of your other hand on the **thumbgrip**. Push

1146 your thumb away from you as far as it will go until the mouthpiece appears and snaps into

1147 position (*see Figure 2*).

1148



1149

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1151

Figure 2

1152 **2. CLICK**

1153 Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the **lever**
1154 away from you as far as it will go until it **clicks** (see *Figure 3*). The DISKUS is now ready to
1155 use.
1156



Figure 3

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1159
1160 Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a
1161 decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the**
1162 **DISKUS is ready:**

- 1163 • **Do not close the DISKUS.**
- 1164 • **Do not tilt the DISKUS.**
- 1165 • **Do not play with the lever.**
- 1166 • **Do not move the lever more than once.**

1167
1168 **3. INHALE**

1169 Before inhaling your dose from the DISKUS, breathe out (exhale) fully while holding the
1170 DISKUS level and away from your mouth (see *Figure 4*). **Remember, never breathe out**
1171 **into the DISKUS mouthpiece.**
1172



Figure 4

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Put the mouthpiece to your lips (*see Figure 5*). Breathe in quickly and deeply through the DISKUS. Do not breathe in through your nose.



Figure 5

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Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as long as is comfortable. Breathe out slowly.

The DISKUS delivers your dose of medicine as a very fine powder. Most patients can taste or feel the powder. Do not use another dose from the DISKUS if you do not feel or taste the medicine.

- 4. Close the DISKUS when you are finished taking a dose so that the DISKUS will be ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the thumbgrip back towards you as far as it will go (*see Figure 6*). The DISKUS will click shut. The lever will automatically return to its original position. The DISKUS is now ready for you

1193 to take your next scheduled dose, due in about 12 hours. (Repeat steps 1 to 4.)
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Figure 6

Remember:

- Never breathe into the DISKUS.
- Never take the DISKUS apart.
- Always ready and use the DISKUS in a level, flat position.
- Do not use the DISKUS with a spacer device.
- Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**
- Always keep the DISKUS in a dry place.
- Never take an extra dose, even if you did not taste or feel the medicine.

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

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