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MEDICATION GUIDE

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

891 Read the Medication Guide that comes with SEREVENT DISKUS before you start using it and
892 each time you get a refill. There may be new information. This Medication Guide does not take
893 the place of talking to your healthcare provider about your medical condition or treatment.
894

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

896 SEREVENT DISKUS is a medicine called a long-acting beta₂-agonist or LABA. LABA
897 medicines are used in patients with asthma, exercise-induced bronchospasm (EIB), and chronic
898 obstructive pulmonary disease (COPD). LABA medicines help the muscles around the airways
899 in your lungs stay relaxed to prevent symptoms, such as wheezing and shortness of breath. These
900 symptoms can happen when the muscles around the airways tighten. This makes it hard to
901 breathe. In severe cases, wheezing can stop your breathing and cause death if not treated right
902 away.
903

- 904 • **In patients with asthma, LABA medicines, such as SEREVENT DISKUS, may increase**
905 **the chance of death from asthma problems.** In a large asthma study, more patients who
906 used salmeterol (SEREVENT) died from asthma problems compared with patients who did
907 not use salmeterol (SEREVENT). Talk with your healthcare provider about this risk and the
908 benefits of treating your asthma with SEREVENT DISKUS.
909
- 910 • **SEREVENT DISKUS does not relieve sudden symptoms. Always have a short-acting**
911 **beta₂-agonist medicine with you to treat sudden symptoms. If you do not have an**
912 **inhaled, short-acting bronchodilator, contact your healthcare provider to have one**
913 **prescribed for you.**
914
- 915 • **Do not stop using SEREVENT DISKUS unless told to do so by your healthcare**
916 **provider because your symptoms might get worse.**

- 917
- 918 • **SEREVENT DISKUS:**
- 919 • **should not be the only medicine prescribed for your asthma**
- 920 • **should be used only if your healthcare provider decides that another**
- 921 **asthma-controller medicine alone does not control your asthma or that you need 2**
- 922 **asthma-controller medicines**
- 923
- 924 • **Call your healthcare provider if breathing problems worsen over time while using**
- 925 **SEREVENT DISKUS. You may need different treatment.**
- 926
- 927 • **Get emergency medical care if:**
- 928 • **breathing problems worsen quickly, and**
- 929 • **you use your short-acting beta₂-agonist medicine, but it does not relieve your**
- 930 **breathing problems**
- 931

932 **What is SEREVENT DISKUS?**

933 SEREVENT DISKUS is a long-acting beta₂-agonist medicine (LABA). SEREVENT DISKUS is

934 used for asthma, exercise-induced bronchospasm (EIB), and chronic obstructive pulmonary

935 disease (COPD) as follows:

936

937 **Asthma**

938 SEREVENT DISKUS is used long term, twice a day, to control symptoms of asthma, and

939 prevent symptoms such as wheezing in adults and children ages 4 and older.

940

941 **Because LABA medicines, such as SEREVENT DISKUS, may increase the chance of death**

942 **from asthma problems, SEREVENT DISKUS is not for adults and children with asthma**

943 **who:**

- 944 • are well controlled with another asthma-controller medicine, such as a low to medium
- 945 dose of an inhaled corticosteroid medicine
- 946 • only need short-acting beta₂-agonist medicines once in awhile
- 947

948 **Exercise-Induced Bronchospasm (EIB)**

949 SEREVENT DISKUS is used for the prevention of wheezing caused by exercise in adults and

950 children 4 years of age and older.

951

952 **Chronic Obstructive Pulmonary Disease (COPD)**

953 SEREVENT DISKUS is used long term, twice a day in controlling symptoms of COPD and

954 preventing wheezing in adults with COPD.

955

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

- 957 **Tell your healthcare provider about all of your health conditions, including if you:**
- 958 • **have heart problems**
 - 959 • **have high blood pressure**
 - 960 • **have seizures**
 - 961 • **have thyroid problems**
 - 962 • **have diabetes**
 - 963 • **have liver problems**
 - 964 • **are pregnant or planning to become pregnant.** It is not known if SEREVENT DISKUS
965 may harm your unborn baby.
 - 966 • **are breastfeeding.** It is not known if SEREVENT DISKUS passes into your milk and if it
967 can harm your baby.
 - 968 • **are allergic to SEREVENT DISKUS, any other medicines, or food products**

969

970 Tell your healthcare provider about all the medicines you take including prescription and
971 non-prescription medicines, vitamins, and herbal supplements. SEREVENT DISKUS and certain
972 other medicines may interact with each other. This may cause serious side effects.

973

974 Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist
975 each time you get a new medicine.

976

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

978 **See the step-by-step instructions for using the SEREVENT DISKUS at the end of this**
979 **Medication Guide.** Do not use the SEREVENT DISKUS unless your healthcare provider has
980 taught you and you understand everything. Ask your healthcare provider or pharmacist if you
981 have any questions.

- 982
- 983 • Children should use SEREVENT DISKUS with an adult's help, as instructed by the child's
984 healthcare provider.
 - 985
 - 986 • Use SEREVENT DISKUS exactly as prescribed. **Do not use SEREVENT DISKUS more**
987 **often than prescribed.**
 - 988
 - 989 • For asthma and COPD, the usual dose is 1 inhalation twice a day (morning and evening). The
990 2 doses should be about 12 hours apart.
 - 991
 - 992 • For preventing exercise-induced bronchospasm, take 1 inhalation at least 30 minutes before
993 exercise. Do not use SEREVENT DISKUS more often than every 12 hours. Do not use extra
994 SEREVENT DISKUS before exercise if you already use it twice a day.
 - 995
 - 996 • If you miss a dose of SEREVENT DISKUS, just skip that dose. Take your next dose at your

997 usual time. Do not take 2 doses at one time.

998

999 • Do not use a spacer device with SEREVENT DISKUS.

1000

1001 • Do not breathe into SEREVENT DISKUS.

1002

1003 • **While you are using SEREVENT DISKUS twice a day, do not use other medicines that**
1004 **contain a long-acting beta₂-agonist or LABA for any reason. Other LABA medicines**
1005 **include ADVAIR DISKUS[®] (fluticasone propionate and salmeterol inhalation powder),**
1006 **ADVAIR[®] HFA (fluticasone propionate and salmeterol) Inhalation Aerosol,**
1007 **FORADIL[®] AEROLIZER[®] (formoterol fumarate inhalation powder), SYMBICORT[®]**
1008 **(budesonide and formoterol fumarate dihydrate) Inhalation Aerosol,**
1009 **PERFOROMIST[™] (formoterol fumarate) Inhalation Solution, and BROVANA[™]**
1010 **(arformoterol tartrate) Inhalation Solution.**

1011

1012 • Do not change or stop any of your medicines used to control or treat your breathing
1013 problems. Your healthcare provider will adjust your medicines as needed.

1014

1015 • Make sure you always have a short-acting beta₂-agonist medicine with you. Use your
1016 short-acting beta₂-agonist medicine if you have breathing problems between doses of
1017 SEREVENT DISKUS.

1018

1019 • **Call your healthcare provider or get medical care right away if:**

1020

- your breathing problems worsen with SEREVENT DISKUS

1021

- you need to use your short-acting beta₂-agonist medicine more often than usual

1022

- your short-acting beta₂-agonist medicine does not work as well for you at relieving
1023 symptoms

1023

- you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
1024 more days in a row

1025

- you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time

1026

- your peak flow meter results decrease. Your healthcare provider will tell you the numbers
1027 that are right for you.

1028

- you have asthma and your symptoms do not improve after using SEREVENT DISKUS
1029 regularly for 1 week.

1030

1031

1032 **What are the possible side effects with SEREVENT DISKUS?**

1033

- **In patients with asthma, LABA medicines, such as SEREVENT, may increase the**
1034 **chance of death from asthma problems. See “What is the most important information I**
1035 **should know about SEREVENT DISKUS?”**

1036

1037 **Other possible side effects with SEREVENT DISKUS include:**

- 1038 • **serious allergic reactions including rash; hives; swelling of the face, mouth, and**
- 1039 **tongue; and breathing problems.** Call your healthcare provider or get emergency
- 1040 medical care if you get any symptoms of a serious allergic reaction.
- 1041 • **increased blood pressure**
- 1042 • **a fast and irregular heartbeat**
- 1043 • **chest pain**
- 1044 • **headache**
- 1045 • **tremor**
- 1046 • **nervousness**
- 1047 • **throat irritation**

1048

1049 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1050

1051 These are not all the side effects with SEREVENT DISKUS. Ask your healthcare provider or

1052 pharmacist for more information.

1053

1054 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-

1055 800-FDA-1088.

1056

1057 **How do I store SEREVENT DISKUS?**

- 1058 • Store SEREVENT DISKUS at room temperature between 68° to 77° F (20° to 25° C).
- 1059 Keep in a dry place away from heat and sunlight.
- 1060 • Safely discard SEREVENT DISKUS 6 weeks after you remove it from the foil pouch, or
- 1061 after the dose indicator reads “0”, whichever comes first.
- 1062 • **Keep SEREVENT DISKUS and all medicines out of the reach of children.**

1063

1064 **General Information about SEREVENT DISKUS**

1065 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not

1066 use SEREVENT DISKUS for a condition for which it was not prescribed. Do not give your

1067 SEREVENT DISKUS to other people, even if they have the same condition. It may harm them.

1068

1069 This Medication Guide summarizes the most important information about SEREVENT

1070 DISKUS. If you would like more information, talk with your healthcare provider or pharmacist.

1071 You can ask your healthcare provider or pharmacist for information about SEREVENT DISKUS

1072 that was written for healthcare professionals. You can also contact the company that makes

1073 SEREVENT DISKUS (toll free) at 1-888-825-5249 or at www.serevent.com.

1074

1075

Instructions for Using SEREVENT DISKUS

1076

Follow the instructions below for using your SEREVENT DISKUS. **You will breathe in**

1077 (inhale) the medicine from the DISKUS. If you have any questions, ask your healthcare
1078 provider or pharmacist.



1079
1080 Take the SEREVENT DISKUS out of the box and foil pouch. Write the **“Pouch opened”** and
1081 **“Use by”** dates on the label on top of the DISKUS. The **“Use by”** date is **6 weeks from date of**
1082 **opening the pouch.**

- 1083
- 1084 • The DISKUS will be in the closed position when the pouch is opened.
 - 1085
 - 1086 • The **dose indicator** on the top of the DISKUS tells you how many doses are left. The
1087 dose indicator number will decrease each time you use the DISKUS. After you have used
1088 55 doses from the DISKUS, the numbers 5 to 0 will appear in **red** to warn you that there
1089 are only a few doses left (*see Figure 1*).

1090



1091

1092

1093

1094 Taking a dose from the DISKUS requires the following 3 simple steps: Open, Click, Inhale.

1095

Figure 1

1096 **1. OPEN**

1097 Hold the DISKUS in one hand and put the thumb of your other hand on the **thumbgrip**.
1098 Push your thumb away from you as far as it will go until the mouthpiece appears and
1099 snaps into position (*see Figure 2*).
1100



1101
1102 Figure 2

1103
1104 **2. CLICK**

1105 Hold the DISKUS in a level, flat position with the mouthpiece towards you. Slide the
1106 **lever** away from you as far as it will go until it **clicks** (*see Figure 3*). The DISKUS is
1107 now ready to use.
1108



1109
1110 Figure 3

1111
1112 Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a
1113 decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the**
1114 **DISKUS is ready:**

- 1115 • **Do not close the DISKUS.**
- 1116 • **Do not tilt the DISKUS.**
- 1117 • **Do not play with the lever.**
- 1118 • **Do not move the lever more than once.**

1120 **3. INHALE**

1121 Before inhaling your dose from the DISKUS, breathe out (exhale) fully while holding the
1122 DISKUS level and away from your mouth (*see Figure 4*). **Remember, never breathe**
1123 **out into the DISKUS mouthpiece.**



1125 Figure 4

1126 Put the mouthpiece to your lips (*see Figure 5*). Breathe in quickly and deeply through the
1127 DISKUS. Do not breathe in through your nose.



1131 Figure 5

1132 Remove the DISKUS from your mouth. Hold your breath for about 10 seconds, or for as
1133 long as you can.

1135 long as is comfortable. Breathe out slowly.

1136

1137 The DISKUS delivers your dose of medicine as a very fine powder. Most patients can
1138 taste or feel the powder. Do not use another dose from the DISKUS if you do not feel or
1139 taste the medicine.

1140

1141 **4. Close the DISKUS when you are finished taking a dose so that the DISKUS will be**
1142 **ready for you to take your next dose.** Put your thumb on the thumbgrip and slide the
1143 thumbgrip back towards you as far as it will go (*see Figure 6*). The DISKUS will click
1144 shut. The lever will automatically return to its original position. The DISKUS is now
1145 ready for you to take your next scheduled dose, due in about 12 hours. (Repeat steps 1 to
1146 4.)

1147



1148

1149

Figure 6

1150

1151 **Remember:**

- 1152 • Never breathe into the DISKUS.
- 1153 • Never take the DISKUS apart.
- 1154 • Always ready and use the DISKUS in a level, flat position.
- 1155 • Do not use the DISKUS with a spacer device.
- 1156 • Never wash the mouthpiece or any part of the DISKUS. **Keep it dry.**
- 1157 • Always keep the DISKUS in a dry place.
- 1158 • Never take an extra dose, even if you did not taste or feel the medicine.

1159

1160 **Rx only**

1161

1162



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1178 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**