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MEDICATION GUIDE

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

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

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

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

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

- 879 • **should only be used if your healthcare provider decides that another asthma-controller**
880 **medicine alone does not control your asthma or that you need 2 asthma-controller**
881 **medicines**
- 882
- 883 • **Call your healthcare provider if breathing problems worsen over time while using**
884 **SEREVENT DISKUS. You may need different treatment.**
- 885
- 886 • **Get emergency medical care if:**
- 887 • **breathing problems worsen quickly, and**
- 888 • **you use your short-acting beta₂-agonist medicine, but it does not relieve your**
889 **breathing problems**
- 890

891 **What is SEREVENT DISKUS?**

892 SEREVENT DISKUS is a long-acting beta₂-agonist medicine (LABA). SEREVENT DISKUS is
893 used for asthma, exercise-induced bronchospasm (EIB), and chronic obstructive pulmonary
894 disease (COPD) as follows:

895

896 **Asthma**

897 SEREVENT DISKUS is used long term, twice a day, to control symptoms of asthma, and
898 prevent symptoms such as wheezing in adults and children ages 4 and older.

899

900 **Because LABA medicines such as SEREVENT DISKUS may increase the chance of death**
901 **from asthma problems, SEREVENT DISKUS is not for adults and children with asthma**
902 **who:**

- 903 • **are well controlled with another asthma-controller medicine, such as a low to medium dose**
904 **of an inhaled corticosteroid**
- 905 • **only need short-acting beta₂-agonist medicines once in awhile**
- 906

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

908 SEREVENT DISKUS is used for the prevention of wheezing caused by exercise in adults and
909 children 4 years of age and older.

910

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

912 SEREVENT DISKUS is used long term, twice a day in controlling symptoms of COPD and
913 preventing wheezing in adults with COPD.

914

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

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

- 917 • **have heart problems**
- 918 • **have high blood pressure**

- 919 • **have seizures**
- 920 • **have thyroid problems**
- 921 • **have diabetes**
- 922 • **have liver problems**
- 923 • **are pregnant or planning to become pregnant.** It is not known if SEREVENT DISKUS
- 924 may harm your unborn baby.
- 925 • **are breastfeeding.** It is not known if SEREVENT DISKUS passes into your milk and if it can
- 926 harm your baby.
- 927 • **are allergic to SEREVENT DISKUS, any other medicines, or food products**

928

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

932

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

935

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

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

941

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

944

- 945 • Use SEREVENT DISKUS exactly as prescribed. **Do not use SEREVENT DISKUS more**
 946 **often than prescribed.**

947

- 948 • For asthma and COPD, the usual dose is 1 inhalation twice a day (morning and evening). The
 949 2 doses should be about 12 hours apart.

950

- 951 • For preventing exercise-induced bronchospasm, take 1 inhalation at least 30 minutes before
 952 exercise. Do not use SEREVENT DISKUS more often than every 12 hours. Do not use extra
 953 SEREVENT DISKUS before exercise if you already use it twice a day.

954

- 955 • If you miss a dose of SEREVENT DISKUS, just skip that dose. Take your next dose at your
 956 usual time. Do not take 2 doses at one time.

957

- 958 • Do not use a spacer device with SEREVENT DISKUS.

- 959
- 960 • Do not breathe into SEREVENT DISKUS.
- 961
- 962 • **While you are using SEREVENT DISKUS twice a day, do not use other medicines that**
- 963 **contain a long-acting beta₂-agonist or LABA for any reason. Other LABA medicines**
- 964 **include ADVAIR DISKUS[®] (fluticasone propionate and salmeterol inhalation powder)**
- 965 **or FORADIL[®] AEROLIZER[™] (formoterol fumarate inhalation powder).**
- 966
- 967 • Do not change or stop any of your medicines used to control or treat your breathing problems.
- 968 Your healthcare provider will adjust your medicines as needed.
- 969
- 970 • Make sure you always have a short-acting beta₂-agonist medicine with you. Use your
- 971 short-acting beta₂-agonist medicine if you have breathing problems between doses of
- 972 SEREVENT DISKUS.
- 973
- 974 • **Call your healthcare provider or get medical care right away if:**
- 975 • your breathing problems worsen with SEREVENT DISKUS
- 976 • you need to use your short-acting beta₂-agonist medicine more often than usual
- 977 • your short-acting beta₂-agonist medicine does not work as well for you at relieving
- 978 symptoms
- 979 • you need to use 4 or more inhalations of your short-acting beta₂-agonist medicine for 2 or
- 980 more days in a row
- 981 • you use 1 whole canister of your short-acting beta₂-agonist medicine in 8 weeks' time
- 982 • your peak flow meter results decrease. Your healthcare provider will tell you the numbers
- 983 that are right for you.
- 984 • you have asthma and your symptoms do not improve after using SEREVENT DISKUS
- 985 regularly for 1 week.
- 986

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

- 988 • **In patients with asthma, LABA medicines such as SEREVENT may increase the**
- 989 **chance of death from asthma problems.** See “What is the most important information I
- 990 should know about SEREVENT DISKUS?”
- 991

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

- 993 • **serious allergic reactions including rash, hives, swelling of the face, mouth, and**
- 994 **tongue, and breathing problems.** Call your healthcare provider or get emergency
- 995 medical care if you get any symptoms of a serious allergic reaction.
- 996 • **increased blood pressure**
- 997 • **a fast and irregular heartbeat**
- 998 • **chest pain**

- 999 • **headache**
- 1000 • **tremor**
- 1001 • **nervousness**
- 1002 • **throat irritation**

1003
1004 Tell your healthcare provider about any side effect that bothers you or that does not go away.

1005
1006 These are not all the side effects with SEREVENT DISKUS. Ask your healthcare provider or
1007 pharmacist for more information.

1008
1009 **How do I store SEREVENT DISKUS?**

- 1010 • Store SEREVENT DISKUS at room temperature between 68° to 77° F (20° to 25° C).
1011 Keep in a dry place away from heat and sunlight.
- 1012 • Safely discard SEREVENT DISKUS 6 weeks after you remove it from the foil pouch, or
1013 after the dose indicator reads “0”, whichever comes first.
- 1014 • **Keep SEREVENT DISKUS and all medicines out of the reach of children.**

1015
1016 **General Information about SEREVENT DISKUS**

1017 Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not
1018 use SEREVENT DISKUS for a condition for which it was not prescribed. Do not give your
1019 SEREVENT DISKUS to other people, even if they have the same condition. It may harm them.

1020 This Medication Guide summarizes the most important information about SEREVENT
1021 DISKUS. If you would like more information, talk with your healthcare provider or pharmacist.
1022 You can ask your healthcare provider or pharmacist for information about SEREVENT DISKUS
1023 that was written for healthcare professionals. You can also contact the company that makes
1024 SEREVENT DISKUS (toll free) at 1-888-825-5249 or at www.serevent.com.

1025
1026 **Instructions for Using SEREVENT DISKUS**

1027 Follow the instructions below for using your SEREVENT DISKUS. **You will breathe-in**
1028 **(inhale) the medicine from the DISKUS.** If you have any questions, ask your healthcare
1029 provider or pharmacist.



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How to Use Your SEREVENT DISKUS

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

- The DISKUS will be in the closed position when the pouch is opened.
- 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*). If you are using a “sample” DISKUS, the numbers 5 to 0 will appear in red after 23 doses.



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Figure 1

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

1. OPEN

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



Figure 2

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2. CLICK

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



Figure 3

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1066 Every time the **lever** is pushed back, a dose is ready to be inhaled. This is shown by a
1067 decrease in numbers on the dose counter. **To avoid releasing or wasting doses once the**
1068 **DISKUS is ready:**

- 1069 • **Do not close the DISKUS.**
- 1070 • **Do not tilt the DISKUS.**
- 1071 • **Do not play with the lever.**
- 1072 • **Do not move the lever more than once.**

1073
1074 **3. INHALE**

1075 Before inhaling your dose from the DISKUS, breathe out (exhale) fully while holding the
1076 DISKUS level and away from your mouth (*see Figure 4*). **Remember, never breathe out**
1077 **into the DISKUS mouthpiece.**

1078



Figure 4

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1082 Put the mouthpiece to your lips (*see Figure 5*). Breathe in quickly and deeply through the
1083 DISKUS. Do not breathe in through your nose.

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



Figure 6

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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.

Rx only



1116

1117 GlaxoSmithKline

1118 Research Triangle Park, NC 27709

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1127 **This Medication Guide has been approved by the U.S. Food and Drug Administration.**