

723 Counsel patients, their caregivers, and their families that AEDs, including ONFI,
724 may increase the risk of suicidal thoughts and behavior and advise them of the
725 need to be alert for the emergence or worsening of symptoms of depression, any
726 unusual changes in mood or behavior, or the emergence of suicidal thoughts,
727 behavior, or thoughts of self-harm. Patients should report behaviors of concern
728 immediately to healthcare providers [*see Warnings and Precautions (5.5)*].

729

730 Use in Pregnancy

731 Instruct patients to notify their healthcare provider if they become pregnant or
732 intend to become pregnant during therapy.

733

734 Encourage patients to enroll in the NAAED Pregnancy Registry if they become
735 pregnant. This registry is collecting information about the safety of antiepileptic
736 drugs during pregnancy. To enroll, patients can call the toll free number 1-888-
737 233-2334. Information on the registry can also be found at the website
738 <http://www.aedpregnancyregistry.org> [*see Use in Specific Populations (8.1)*].

739

740 Use in Nursing

741 Instruct patients to notify their physician if they are breast feeding or intend to
742 breast feed during therapy [*see Use in Specific Populations (8.3)*].

743

744 Manufactured by: Catalent Pharma Solutions, LLC
745 Winchester, KY 40391, U.S.A.

746

747 For: Lundbeck Inc.
748 Deerfield, IL 60015, U.S.A.

749

750 **MEDICATION GUIDE**

751

752 **ONFI™ (ON-fee)** 753 **(clobazam)** 754 **Tablets**

755

756

757

758 Read this Medication Guide before you start taking ONFI and each time you
759 get a refill. There may be new information. This information does not take
760 the place of talking to your healthcare provider about your medical condition
761 or treatment.

762

763

764 **What is the most important information I should know about ONFI?**

765

766 **Do not stop taking ONFI without first talking to your healthcare**
767 **provider.** Stopping ONFI suddenly can cause serious problems.

768

769

ONFI can cause serious side effects, including:

770

771

1. ONFI can make you sleepy or dizzy, slow your thinking, and make you clumsy which may get better over time.

772

773

774

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ONFI affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking ONFI until you talk to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, ONFI may make your sleepiness or dizziness much worse.

775

776

777

778

779

780

781

2. ONFI can cause withdrawal symptoms.

782

783

- Do not stop taking ONFI all of a sudden without first talking to a healthcare provider. Stopping ONFI suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.

784

785

786

787

788

789

- Talk to your healthcare provider about slowly stopping ONFI to avoid withdrawal symptoms.

790

791

792

793

3. ONFI can be abused and cause dependence.

794

795

- Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.

796

797

798

799

ONFI is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep ONFI in a safe place to prevent misuse and abuse. Selling or giving away ONFI may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

800

801

802

803

804

805

806

4. Like other antiepileptic drugs, ONFI may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

807

808

809

Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

810

811

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression

812

813

814

- 815 • new or worse anxiety
- 816 • feeling agitated or restless
- 817 • panic attacks
- 818 • trouble sleeping (insomnia)
- 819 • new or worse irritability
- 820 • acting aggressive, being angry, or violent
- 821 • acting on dangerous impulses
- 822 • an extreme increase in activity and talking (mania)
- 823 • other unusual changes in behavior or mood

824

825 **How can I watch for early symptoms of suicidal thoughts and**
826 **actions?**

827

- 828 • Pay attention to any changes, especially sudden changes, in mood,
829 behaviors, thoughts, or feelings.
- 830 • Keep all follow-up visits with your healthcare provider as scheduled.

831

832 Call your healthcare provider between visits as needed, especially if you are
833 worried about symptoms.

834

835 Suicidal thoughts or actions can be caused by things other than medicines.
836 If you have suicidal thoughts or actions, your healthcare provider may check
837 for other causes.

838

839 **What is ONFI?**

840

841 ONFI is a prescription medicine used along with other medicines to treat
842 seizures associated with Lennox-Gastaut syndrome in people 2 years of age
843 or older.

844

845 It is not known if ONFI is safe and effective in children less than 2 years old.

846

847 **What should I tell my healthcare provider before taking ONFI?**

848

849 **Before you take ONFI, tell your healthcare provider if you:**

850

- 851 • have liver or kidney problems
- 852 • have lung problems (respiratory disease)
- 853 • have or have had depression, mood problems, or suicidal thoughts or
854 behavior
- 855 • have any other medical conditions
- 856 • use birth control medicine. ONFI may cause your birth control
857 medicine to be less effective. Talk to your healthcare provider about
858 the best birth control method to use.
- 859 • are pregnant or plan to become pregnant. **ONFI may harm your**
860 **unborn baby.**

861

- 862
- 863
- 864
- 865
- 866
- 867
- 868
- 869
- 870
- 871
- Tell your healthcare provider right away if you become pregnant while taking ONFI. You and your healthcare provider will decide if you should take ONFI while you are pregnant.
 - Children born to mothers receiving benzodiazepine medications (including ONFI) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, dangerously low body temperature, and withdrawal symptoms.
- 872
- If you become pregnant while taking ONFI, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
 - ONFI can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take ONFI. You and your healthcare provider should decide if you will take ONFI or breast feed. You should not do both.
- 873
- 874
- 875
- 876
- 877
- 878
- 879
- 880
- 881

882 **Tell your healthcare provider about all the medicines you take,**
883 including prescription and nonprescription medicines, vitamins, and herbal
884 supplements. Taking ONFI with certain other medicines can cause side
885 effects or affect how well ONFI or the other medications work. Do not start
886 or stop other medicines without talking to your healthcare provider.

887

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

890

891 **How should I take ONFI?**

- 892
- ONFI can be taken whole, or crushed and mixed in applesauce.
 - Take ONFI exactly as your healthcare provider tells you to take it.
 - Your healthcare provider will tell you how much ONFI to take and when to take it.
- 893
- 894
- 895
- 896
- 897

898 Your healthcare provider may change your dose if needed. Do not change
899 your dose of ONFI without talking to your healthcare provider.

- 900
- Do not stop taking ONFI without first talking to your healthcare provider.
 - Stopping ONFI suddenly can cause serious problems.
- 901
- 902
- 903
- 904

905 If you take too much ONFI, call your healthcare provider or go to the nearest
906 hospital emergency room right away.

907

908 **What should I avoid while taking ONFI?**

- 909
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ONFI affects you.
- 910
- Do not drink alcohol or take other medicines that may make you sleepy or dizzy while taking ONFI until you talk to your healthcare provider. When taken with alcohol or medicines that cause sleepiness or dizziness, ONFI may make your sleepiness or dizziness much worse.
- 911
- 912
- 913
- 914
- 915

916 **What are the possible side effects of ONFI?**

917

918 **ONFI may cause serious side effects, including:**

919

920

921 **See “What is the most important information I should know about ONFI?”**

922

923

924 The most common side effects of ONFI include:

925

- sleepiness
 - drooling
 - constipation
 - cough
 - pain with urination
 - fever
 - acting aggressive, being angry, or violent
 - difficulty sleeping
 - slurred speech
 - tiredness
 - problems with breathing
- 926
- 927
- 928
- 929
- 930
- 931
- 932
- 933
- 934
- 935
- 936
- 937

938 These are not all the possible side effects of ONFI. For more information, ask your healthcare provider or pharmacist.

939

940

941 Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

942

943

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

945

946

947 **How should I store ONFI?**

948

- Store ONFI between 68°F to 77°F (20°C to 25°C).
- 949
- 950

951 **Keep ONFI and all medicines out of the reach of children.**

952

953 **General Information about the safe and effective use of ONFI.**

954

955

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ONFI for a condition for which it was not

956 prescribed. Do not give ONFI to other people, even if they have the same
957 symptoms that you have. It may harm them.

958

959 This Medication Guide summarizes the most important information about
960 ONFI. If you would like more information, talk with your healthcare provider.
961 You can ask your pharmacist or healthcare provider for information about
962 ONFI that is written for health professionals.

963

964 For more information about ONFI, go to www.lundbeckinc.com or call
965 Lundbeck Inc. at 1-888-514-5204.

966

967 **What are the ingredients in ONFI?**

968

969 **Active ingredient:** clobazam

970

971 **Inactive ingredients:** corn starch, lactose monohydrate, magnesium
972 stearate, silicon dioxide, and talc.

973

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

976

977 Manufactured by: Catalent Pharma Solutions, LLC
978 Winchester, KY 40391, U.S.A.

979

980 For: Lundbeck Inc.
981 Deerfield, IL 60015, U.S.A.

982



983

984

985

986 TM Trademark of Lundbeck Inc.

987

988 **October 2011**

989