

HOW SUPPLIED

TRIDIONE Dulcet[®] Tablets (trimethadione tablets) are supplied as white, chewable tablets bearing the Abbott Logo and a two-letter Abbo-Code designation LE for the 150 mg tablet, in bottles of 100 (NDC 0074-3753-01).

Recommended Storage

Store Dulcet tablets in refrigerator 36° to 46°F (2° - 8°C) to minimize crystallization. However some crystallization not harmful to product may occur. Keep tightly closed.

[®]Dulcet–Sweetened tablets, Abbott.

Abbott Laboratories

North Chicago, IL 60064, U.S.A.

FDA-APPROVED MEDICATION GUIDE

MEDICATION GUIDE

TRIDIONE (tri-'dI-'On)

(trimethadione)

Tablets

Read this Medication Guide before you start taking TRIDIONE and each time you get a refill. There may be new information. This information 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 TRIDIONE?

Do not stop taking TRIDIONE without first talking to your healthcare provider.

Stopping TRIDIONE suddenly can cause serious problems.

TRIDIONE can cause serious side effects, including:

1. **Rash.** This may need to be treated in a hospital and may be life-threatening.

Call your healthcare provider right away if you have any of these symptoms:

- skin rash
- hives
- sores in your mouth

2. **Blood problems that can be life-threatening. Call your healthcare provider right away if you have any of these symptoms:**
 - Fever, swollen glands, or sore throat that come and go or do not go away
 - Frequent infections or an infection that does not go away
 - Easy bruising
 - Red or purple spots on your body
 - Bleeding gums or nose bleeds
 - Severe fatigue or weakness
3. **Liver problems. Call your healthcare provider right away if you have any of these symptoms:**
 - yellowing of your skin or the whites of your eyes (jaundice)
 - dark urine
 - nausea or vomiting
 - loss of appetite
 - pain on the right side of your stomach (abdomen)
4. **Kidney problems that may be life-threatening.**
5. **Eye problems. Call your healthcare provider right away if you have any new changes in your vision such as:**
 - problems seeing in bright light
 - blurred vision
6. **Birth defects in your unborn baby.**
 - **Women who can become pregnant should talk to their healthcare provider about using other possible treatments instead of TRIDIONE. If the decision is made to use TRIDIONE, women should use effective birth control (contraception).** Talk with your healthcare provider if you are pregnant or plan to become pregnant. Birth defects may occur even in children born to women who are not taking any medicines and do not have other risk factors.
 - Tell your healthcare provider right away if you become pregnant while taking TRIDIONE. You and your healthcare provider should decide if you will continue to take TRIDIONE while you are pregnant.
 - If you become pregnant while taking TRIDIONE, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.

- Tell your healthcare provider right away if you are breastfeeding or plan to breastfeed. It is unknown if TRIDIONE passes into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TRIDIONE.

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

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

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

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

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop TRIDIONE without first talking to a healthcare provider. Stopping TRIDIONE suddenly can cause serious problems. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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

What is TRIDIONE?

TRIDIONE is a prescription medicine used to treat absence (petit mal) seizures that are not controlled with other drugs.

Who should not take TRIDIONE?

Do not take TRIDIONE if you are allergic to trimethadione or any of the ingredients in TRIDIONE. See the end of this leaflet for a complete list of ingredients in TRIDIONE.

What should I tell my healthcare provider before taking TRIDIONE?

Before you take TRIDIONE, tell your healthcare provider if you have or have had:

- blood problems
- kidney problems
- liver problems
- eye problems
- depression, mood problems or suicidal thoughts or behavior
- any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I take TRIDIONE?

- Take TRIDIONE exactly as your healthcare provider tells you.
- TRIDIONE can be chewed or swallowed whole.
- Your healthcare provider may change your dose of TRIDIONE. Do not change your dose of TRIDIONE without talking to your healthcare provider.
- If you take too much TRIDIONE, call your healthcare provider or local Poison Control Center right away.
- Do not stop taking TRIDIONE without talking to your healthcare provider. Stopping TRIDIONE suddenly can cause serious problems, including seizures that will not stop (status epilepticus).

What should I avoid while taking TRIDIONE?

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

What are the possible side effects of TRIDIONE?

See “What is the most important information I should know about TRIDIONE?”.

TRIDIONE may cause other serious side effects, including:

- **Symptoms that are like the symptoms of lupus or myasthenia gravis. Call your healthcare provider right away if you have any of these symptoms:**
 - droopy eyelids
 - a rash on your cheeks or other parts of your body
 - sensitivity to the sun
 - new joint or muscle pains
 - chest pain or shortness of breath
 - swelling of your feet, ankles, and legs
 - weakness of your arms or legs
 - problems swallowing
 - speech problems
 - swollen glands (enlarged lymph nodes)

The most common side effects of TRIDIONE include:

- nausea
- sleepiness
- tiredness
- increase in seizures
- feelings of anger and frustration
- changes in behavior

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

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

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

How should I store TRIDIONE?

- Store TRIDIONE in the refrigerator at 36 to 46⁰F (2 to 8⁰C).

- Keep TRIDIONE in a tightly closed container.

Keep TRIDIONE and all medicines out of the reach of children.

General Information about TRIDIONE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRIDIONE for a condition for which it was not prescribed. Do not give TRIDIONE to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about TRIDIONE. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about TRIDIONE that is written for health professionals. For more information, go to www.rxabbott.com or call 1-800-633-9110.

What are the ingredients in TRIDIONE?

Active ingredient: trimethadione

Inactive ingredient: corn starch, lactose, magnesium stearate, magnesium trisilicate, sucrose and natural/synthetic flavor

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