PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[Pr] ZARONTIN

Ethosuximide capsules U.S.P.

Capsules, 250 mg, for oral administration

USP

[Pr] ZARONTIN SYRUP

Ethosuximide oral solution B.P.

Syrup, 250 mg / 5 mL (50 mg / mL), for oral administration

B.P.

Anticonvulsant

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RECENT MAJOR LABEL CHANGES

7 WARNINGS AND PRECAUTIONS, Hematologic	07/2022
7 WARNINGS AND PRECAUTIONS, Skin	07/2022

TABLE OF CONTENTS

Sections or subsections that are not applicable at the time of authorization are not listed.

RECENT MAJOR LABEL CHANGES 2

TABLE OF CONTENTS 2

PART I: HEALTH PROFESSIONAL INFORMATION 4

1 INDICATIONS 4

1.1 Pediatrics 4

1.2 Geriatrics 4

2 CONTRAINDICATIONS 4

3 SERIOUS WARNINGS AND PRECAUTIONS BOX 4

4 DOSAGE AND ADMINISTRATION 4

4.1 Dosing Considerations 4

4.2 Recommended Dose and Dosage Adjustment 4

4.4 Administration 5

4.5 Missed Dose 5

5 OVERDOSAGE 5

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING 5

7 WARNINGS AND PRECAUTIONS 6

7.1 Special Populations 8

7.1.1 Pregnant Women 8

7.1.2 Breast-feeding 8

7.1.3 Pediatrics 8

7.1.4 Geriatrics 8

8 ADVERSE REACTIONS 9

8.5 Post-Market Adverse Reactions 9

9 DRUG INTERACTIONS 9

9.2 Drug Interactions Overview 9

9.4 Drug-Drug Interactions 9
9.5 Drug-Food Interactions 10
9.6 Drug-Herb Interactions 10
9.7 Drug-Laboratory Test Interactions 10
10 CLINICAL PHARMACOLOGY 10
10.3 Pharmacokinetics 10
11 STORAGE, STABILITY AND DISPOSAL 10
12 SPECIAL HANDLING INSTRUCTIONS 11
PART II: SCIENTIFIC INFORMATION 12
13 PHARMACEUTICAL INFORMATION 12
14 CLINICAL TRIALS 12
15 MICROBIOLOGY 12
16 NON-CLINICAL TOXICOLOGY 12
PATIENT MEDICATION INFORMATION 13

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

ZARONTIN / ZARONTIN SYRUP (ethosuximide) is indicated for the control of absence (petit mal) epilepsy.

1.1 Pediatrics

Pediatrics (3-17 years): Safety and effectiveness in pediatric patients below the age of 3 years have not been established (see 4.2 Recommended Dose and Dosage Adjustment).

1.2 Geriatrics

No data are available to Health Canada. Caution should be exercised in dose selection for an elderly patient, recognizing the more frequent hepatic and renal dysfunctions.

2 CONTRAINDICATIONS

- ZARONTIN / ZARONTIN SYRUP is contraindicated in patients who are hypersensitive to ethosuximide or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.
- ZARONTIN / ZARONTIN SYRUP should not be used in patients who are hypersensitive to succinimides or components of these products.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions
Blood dyscrasias, including with fatal outcomes, have been reported to be associated with the use of ethosuximide; therefore, periodic blood counts should be performed. Should signs and/or symptoms of infection (e.g., sore throat, fever) develop, blood count determinations should be considered at that point (see 7 WARNINGS AND PRECAUTIONS, Hematologic).

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

As with other anticonvulsants, it is important to proceed slowly when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.

Patients taking ethosuximide should be advised of the importance of adhering strictly to the prescribed dosage regimen.

4.2 Recommended Dose and Dosage Adjustment

Initial dose: children aged 3 to 6 years, 250 mg daily; older patients, 500 mg daily in divided doses. The dose thereafter must be individualized according to response and tolerance. Dosage should be increased by small increments: e.g. increase daily dose by 250 mg every 4 to 7 days until control is

achieved with minimal side effects. Daily dosage of 1 to 1.5 g in divided doses frequently controls seizures; however, it may be necessary to exceed this amount by slow increases and careful evaluation of patient's response. Dosage exceeding 1.5 g daily, in divided doses, should be administered only under the strictest supervision of the physician. The optimal dose for most children is 20 mg/kg/day. This dose has given average plasma levels within the accepted therapeutic range of 280 to 710 μmol/L (40 to 100 μg/mL). Subsequent dose schedules can be based on effectiveness and plasma level determinations.

Ethosuximide may be administered in combination with other anticonvulsants when other forms of epilepsy coexist with absence (petit mal). The optimal dosage for most children is 20 mg/kg/day.

4.4 Administration

Ethosuximide can be taken with or without food.

Syrup: Advise the patient to carefully measure the dose using a measuring device/spoon. A household spoon should not be used to avoid dosing errors.

4.5 Missed Dose

In case of missed dose, the next dose should be taken as scheduled. A double dose should not be taken.

5 OVERDOSAGE

Symptoms: Acute overdoses may produce nausea, vomiting, and CNS depression including coma with respiratory depression. A relationship between ethosuximide toxicity and its plasma levels has not been established. The therapeutic range is 280 to 710 μmol/L, although levels as high as 1,050 μmol/L have been reported without signs of toxicity.

Treatment: Treatment should include emesis (unless the patient is or could rapidly become obtunded, comatose, or convulsing) or gastric lavage, activated charcoal, cathartics and general supportive measures. Hemodialysis may be useful to treat ethosuximide overdose. Forced diuresis and exchange transfusions are ineffective.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Oral	Capsules 250 mg	D&C Yellow No. 10, FD&C Red No. 3, gelatin, glycerin, polyethylene glycol and sorbitol
Oral	Syrup 250 mg/5 mL (50 mg/mL)	Alcohol, citric acid anhydrous, FD&C Yellow No. 6, FD&C Red No. 3, flavoring agents, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose and vanillin.

ZARONTIN: 250 mg ethosuximide per capsule. Available in bottles of 100.

ZARONTIN SYRUP: Each 5 mL contains 250 mg ethosuximide. Alcohol: 3%. Energy: 62.76 kJ (15 kcal)/5 mL. Sodium: <1 mmol (6.7 mg)/5 mL. Gluten-, lactose-, parabens-, sulfite- and tartrazine-free. Available in bottles of 500 mL.

7 WARNINGS AND PRECAUTIONS

Please see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

Driving and Operating Machinery

Ethosuximide may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a motor vehicle or other such activity requiring alertness; therefore the patient should be cautioned accordingly.

Hematologic

Blood dyscrasias, including some with fatal outcomes, have been reported to be associated with the use of ethosuximide; therefore, periodic blood counts should be performed. Should signs and/or symptoms of infection (e.g., sore throat, fever) develop, blood count determinations should be considered at that point. Patients should be instructed to promptly contact their physician if they develop signs and/or symptoms (e.g., sore throat, fever) suggesting an infection.

Drug-Induced Immune Thrombocytopenia

Drug-induced immune thrombocytopenia (DITP) has been reported with ethosuximide. In the reported cases, the onset of symptoms occurred 1 to 3 weeks after initiation of ethosuximide; one patient had recurrence of symptoms within 1 day of a subsequent re-challenge with the drug. In those cases in which the platelet count was specified, the nadir was 2,000 and 3,000/mm^3. When DITP is suspected, discontinue ZARONTIN / ZARONTIN SYRUP, monitor serial platelet counts, and treat as appropriate. If possible, assess the presence of drug-dependent antiplatelet antibodies. Avoid future use of ZARONTIN / ZARONTIN SYRUP in patients with history of ethosuximide-induced DITP.

Hepatic/Biliary/Pancreatic

Ethosuximide is capable of producing morphological and functional changes in the animal liver. In humans, abnormal liver function studies have been reported.

Administer ethosuximide with extreme caution to patients with known liver disease. Periodic liver function studies are advised for all patients receiving the drug.

Immune

Case of systemic lupus erythematosus have been reported with the use of ethosuximide. The physician should be alert to this possibility.

Neurologic

Ethosuximide, when used alone in mixed types of epilepsy, may increase the frequency of grand mal seizures in some patients.

Psychiatric

Suicidal Ideation and Behavior

Suicidal ideation and behavior have been reported in patients treated with antiepileptic agents in several indications.

All patients treated with antiepileptic drugs, irrespective of indication, should be monitored for sign of suicidal ideation and behavior and appropriate treatment should be considered.

Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge.

An FDA meta-analysis of randomized placebo controlled trials, in which antiepileptic drugs were used for various indications, has shown a small increased risk of suicidal ideation and behavior in patients treated with these drugs. The mechanism of this risk is not known.

There were 43892 patients treated in the placebo controlled clinical trials that were included in the meta-analysis. Approximately 75% of patients in these clinical trials were treated for indications other than epilepsy and, for the majority of non-epilepsy indications the treatment (antiepileptic drug or placebo) was administered as monotherapy. Patients with epilepsy represented approximately 25% of the total number of patients treated in the placebo controlled clinical trials and, for the majority of epilepsy patients, treatment (antiepileptic drug or placebo) was administered as adjunct to other antiepileptic agents (i.e., patients in both treatment arms were being treated with one or more antiepileptic drug). Therefore, the small increased risk of suicidal ideation and behavior reported from the metanalysis (0.43% for patients on antiepileptic drugs compared to 0.24% for patients on placebo) is based largely on patients that received monotherapy treatment (antiepileptic drug or placebo) for non-epilepsy indications. The study design does not allow an estimation of the risk of suicidal ideation and behavior for patients with epilepsy that are taking antiepileptic drugs, due both to this population being the minority in the study, and the drug-placebo comparison in this population being confounded by the presence of adjunct antiepileptic drug treatment in both arms.

Renal

In humans, abnormal renal function studies have been reported.

Administer ethosuximide with extreme caution to patients with known renal disease. Periodic urinalysis studies are advised for all patients receiving the drug.

Skin

Serious dermatologic reactions, including Stevens-Johnson syndrome (SJS), have been reported with ethosuximide treatment. SJS can be fatal. The onset of symptoms is usually within 28 days, but can occur later. ZARONTIN / ZARONTIN SYRUP should be discontinued at the first sign of a rash, unless the rash is clearly not drug-related. If signs or symptoms suggest SJS, use of this drug should not be resumed and alternative therapy should be considered.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multi organ hypersensitivity, has occurred with ZARONTIN / ZARONTIN SYRUP. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematologic abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. This disorder is variable in its expression, and other organ systems not noted here may be involved. It is important to note that early manifestations of

hypersensitivity (e.g. fever, lymphadenopathy) may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. ZARONTIN / ZARONTIN SYRUP should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

7.1 Special Populations

7.1.1 Pregnant Women

Recent reports indicate an association between the use of anticonvulsant drugs and an elevated incidence of birth defects in children born to epileptic women taking such medication during pregnancy. The incidence of congenital malformations in the general population is regarded to be approximately 2%; in children of treated epileptic women this incidence may be increased 2 to 3 fold. The increase is largely due to specific defects, e.g., congenital malformations of the heart, and cleft lip and/or palate. Nevertheless, the great majority of mothers receiving anticonvulsant medications deliver normal infants.

Data are more extensive with respect to phenytoin and phenobarbital, but these drugs are also the most commonly prescribed anticonvulsants. Some reports indicate a possible similar association with the use of other anticonvulsants, including trimethadione and paramethadione. However, the possibility also exists that other factors, e.g., genetic predisposition or the epileptic condition itself may contribute to or may be mainly responsible for the higher incidence of birth defects.

Anticonvulsant drugs should not be discontinued in patients in whom the drug is administered to prevent major seizures, because of the strong possibility of precipitating status epilepticus with attendant hypoxia and risk to both the mother and the unborn child. With regard to drugs given for minor seizures, the risk of discontinuing medication prior to or during pregnancy should be weighed against the risk of congenital defects in the particular case and with the particular family history.

Epileptic women of childbearing age should be encouraged to seek professional counsel and should report the onset of pregnancy promptly to their physician. Where the necessity for continued use of antiepileptic medication is in doubt, appropriate consultation might be indicated.

The preceding considerations should be borne in mind and ethosuximide should be used in women of childbearing potential only when the expected benefits to the patient warrant the possible risk to a fetus.

7.1.2 Breast-feeding

Mothers receiving ethosuximide should not breast-feed their infants. Ethosuximide is excreted in human milk.

7.1.3 Pediatrics

Safety and effectiveness in pediatric patients below the age of 3 years have not been established (see 4 DOSAGE AND ADMINISTRATION).

7.1.4 Geriatrics

No data are available to Health Canada.

8 ADVERSE REACTIONS

8.5 Post-Market Adverse Reactions

Gastrointestinal: Gastrointestinal symptoms occur frequently and include anorexia, vague gastric upset, nausea and vomiting, cramps, epigastric and abdominal pain, weight loss, and diarrhea. There have been reports of gum hypertrophy and swelling of the tongue.

Genitourinary: microscopic hematuria and vaginal bleeding.

Hemopoietic: Leukopenia, agranulocytosis, pancytopenia, aplastic anemia, with or without bone marrow suppression, eosinophilia, and thrombocytopenia.

Integumentary: Dermatologic manifestations which have occurred with the administration of ethosuximide have included urticarial, Stevens-Johnson syndrome (SJS), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), systemic lupus erythematosus, and pruritic erythematous rashes.

Miscellaneous: myopia and hirsutism.

Nervous system: Neurologic and sensory reactions reported during therapy with ethosuximide have included drowsiness, headache, dizziness, euphoria, hiccups, irritability, hyperactivity, lethargy, fatigue, and ataxia. Psychiatric or psychological aberrations associated with ethosuximide administration have included disturbances of sleep, night terrors, inability to concentrate, and aggressiveness. These effects may be noted particularly in patients who have previously exhibited psychological abnormalities. There have been rare reports of paranoid psychosis, increased libido, and increased state of depression with overt suicidal intentions.

9 DRUG INTERACTIONS

9.2 Drug Interactions Overview

Since ethosuximide may interact with concurrently administered antiepileptic drugs, periodic serum level determinations of these drugs may be necessary (refer to Table 2).

9.4 Drug-Drug Interactions

The drugs listed in this table are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Table 2 - Established or Potential Drug-Drug Interactions

Proper/Common name	Source of Evidence	Effect	Clinical comment
Anticonvulsant such as phenytoin, phenobarbital, valproic acid and lamotrigine.	T, C	Ethosuximide may elevate phenytoin serum levels. Valproic acid has been reported to both increased and decrease ethosuximide levels.	Periodic serum level determinations of these drugs may be necessary during treatment.

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.3 Pharmacokinetics

Absorption

ZARONTIN / ZARONTIN SYRUP (ethosuximide) is completely and rapidly absorbed from the gastrointestinal tract. Peak plasma levels occur 1 to 7 hours after a single oral dose.

Distribution:

Ethosuximide is not significantly bound to plasma proteins; therefore, the drug is present in saliva and CSF in concentrations approximately equal to that of the plasma. Therapeutic concentrations are in the range of 280 to 710 mcmol/L (40 to 100 g/mL).

Metabolism:

Ethosuximide is extensively metabolized to at least 3 plasma metabolites.

Elimination

The elimination half-life for the drug is 40 to 60 hours in adults and 30 hours in children. Only 12 to 20% of the drug is excreted unchanged in the urine.

11 STORAGE, STABILITY AND DISPOSAL

Store ZARONTIN capsules between 15 and 25 °C and protect from heat.

Store ZARONTIN SYRUP between 15 and 25 °C and protect from freezing and light.

Keep out of the reach and sight of children.

12 SPECIAL HANDLING INSTRUCTIONS

No special handling instructions.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

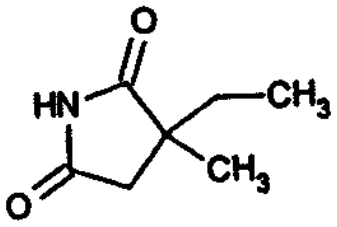
Drug Substance

Proper name: Ethosuximide

Chemical name: 3-ethyl-3-methyl-2, 5-pyrrolidinedione, 3-ethyl-3-methyl-, (±)-.

Molecular formula and molecular mass: $C_7H_{11}NO_2$ - 141.17 g/mol

Structural formula:



14 CLINICAL TRIALS

This information is not available for this drug product.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

There have been no adequate, well-controlled studies on the carcinogenicity, mutagenicity, or impairment of fertility of this product.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr] ZARONTIN
Ethosuximide capsules U.S.P.

and

[Pr] ZARONTIN SYRUP
Ethosuximide oral solution B.P.

Read this carefully before you start taking **ZARONTIN / ZARONTIN SYRUP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ZARONTIN / ZARONTIN SYRUP**.

Serious Warnings and Precautions

Blood Dyscrasias: Diseases of the blood, that can be fatal, can occur while you take ZARONTIN / ZARONTIN SYRUP. You will have regular blood tests while you are taking ZARONTIN / ZARONTIN SYRUP to check for these side effects. Talk to your healthcare professional as soon as possible if you develop any sign or symptom of infection, such as sore throat or fever.

What is ZARONTIN / ZARONTIN SYRUP used for?

ZARONTIN / ZARONTIN SYRUP is used to control absence (petit mal) seizures.

How does ZARONTIN / ZARONTIN SYRUP work?

ZARONTIN / ZARONTIN SYRUP is an anticonvulsant drug. It is used to treat epilepsy. The exact mechanism of action is not entirely understood.

What are the ingredients in ZARONTIN / ZARONTIN SYRUP?

Medicinal ingredients: Ethosuximide

Non-medicinal ingredients:

- **ZARONTIN**: D&C Yellow No. 10, FD&C Red No. 3, gelatin, glycerin, polyethylene glycol and sorbitol.
- **ZARONTIN SYRUP**: alcohol, citric acid anhydrous, FD&C Yellow No. 6, FD&C Red No. 3, flavoring agents, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sucrose and vanillin.

ZARONTIN / ZARONTIN SYRUP comes in the following dosage forms:

- **ZARONTIN:** Capsules 250 mg
- **ZARONTIN SYRUP:** Syrup 250 mg / 5mL

Do not use ZARONTIN / ZARONTIN SYRUP if:

- you are allergic to ethosuximide or any other ingredient of ZARONTIN or ZARONTIN SYRUP (see **What are the ingredients in ZARONTIN / ZARONTIN SYRUP?**);
- you are allergic to any succinimide medicines, also used to treat epilepsy, or components of these products.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ZARONTIN / ZARONTIN SYRUP. Talk about any health conditions or problems you may have, including if you:

- have liver or kidney problems
- have or have had depression or mood problems
- have or have had grand mal seizures
- have a mixed type of epilepsy
- have lupus, an autoimmune disease

Other warnings you should know about:

Mental health problems: Some people have thoughts of suicide or hurting themselves while taking medications to prevent seizures such as ZARONTIN / ZARONTIN SYRUP. Talk to your healthcare professional or get immediate medical help if this happens to you.

Severe skin reactions: Serious skin reactions, that can be fatal, can happen in people taking ZARONTIN / ZARONTIN SYRUP. These reactions include Stevens-Johnson syndrome (SJS) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Get immediate medical help if you develop a rash at any time while you are taking ZARONTIN / ZARONTIN SYRUP. See the **Serious side effects and what to do about them** table, below for information of these and other serious side effects.

Pregnancy and Breastfeeding:

- You should not get pregnant while you are taking ZARONTIN / ZARONTIN SYRUP.
- Women who take anticonvulsant drugs, like ZARONTIN / ZARONTIN SYRUP, during pregnancy have a higher risk of having babies born with birth defects.
- Talk to your healthcare professional immediately if you get pregnant or think you might be pregnant while you are taking ZARONTIN / ZARONTIN SYRUP.
- If you get pregnant while taking ZARONTIN / ZARONTIN SYRUP, talk to your healthcare professional about registering with the North American Antiepileptic Drug Pregnancy Registry. The purpose of this registry is to collect information about the safety of medicines used to treat seizures during pregnancy. You can enroll in this registry by calling 1-888-233-2334. Information on the registry can also be found on the following website: http://aedpregnancyregistry.org/
- Do not breastfeed while you are taking ZARONTIN / ZARONTIN SYRUP. ZARONTIN / ZARONTIN SYRUP passed into breastmilk. Talk to your healthcare professional about other ways to feed your baby.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to ZARONTIN / ZARONTIN SYRUP.

Blood tests and monitoring: ZARONTIN / ZARONTIN SYRUP can cause abnormal blood and urine tests. You will have regular blood and urine tests while you are taking ZARONTIN / ZARONTIN SYRUP to monitor the health of your blood cells as well as your liver and kidneys. Your healthcare professional will decide when to perform blood and urine tests and will interpret the results. If you miss an appointment talk to your healthcare professional as soon as possible to reschedule.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ZARONTIN / ZARONTIN SYRUP:

- other anticonvulsant drugs, used to treat epilepsy, such as phenytoin, phenobarbital or valproic acid
- lamotrigine, an anticonvulsant drug used in the treatment of epilepsy and bipolar disorder.

Do not start or stop other medicines without talking to your healthcare professional. The blood level of ZARONTIN / ZARONTIN SYRUP and any other anticonvulsant drugs you are taking may need to be checked by a blood test.

How to take ZARONTIN / ZARONTIN SYRUP:

- Take ZARONTIN / ZARONTIN SYRUP exactly as your healthcare professional tells you.
- Your healthcare professional will start you on a low dose and slowly increase your dose to find the right dose for you. This might take weeks or months.
- Do NOT stop taking ZARONTIN / ZARONTIN SYRUP or change your dose without talking to your healthcare professional. This can cause your seizures to get worse or cause serious side effects.
- If you are taking ZARONTIN SYRUP carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.
- ZARONTIN / ZARONTIN SYRUP can be taken with or without food.
- This medication has been prescribed specifically for you. Do NOT give it to anyone else. It may harm them, even if their symptoms seem to be similar to yours.

Usual dose:

Adult: 250 mg twice daily

Children (3 – 17 years of age): Your healthcare professional will decide on the dose that is right for your child based on their body weight.

Overdose:

If you think you, or a person you are caring for, have taken too much ZARONTIN / ZARONTIN SYRUP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of ZARONTIN / ZARONTIN SYRUP, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and go back to your usual dosing schedule. Do not double the dose to catch up.

What are possible side effects from using ZARONTIN / ZARONTIN SYRUP?

These are not all the possible side effects you may have when taking ZARONTIN / ZARONTIN SYRUP. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea, diarrhea, vomiting, indigestion
- Loss of appetite, stomach cramps or pain
- Weight loss
- Hiccups
- Trouble sleeping, night terrors
- Trouble concentrating
- Drowsiness, dizziness, lethargy, sedation
- Euphoria, hyperactivity, irritability

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
UNCOMMON			
Mental health problems: thoughts of suicide or hurting yourself			✔
Allergic reactions: swelling in the eyes, lips, mouth, tongue, face and throat, itching, rash, hives, difficulty swallowing or breathing			✔
Decreased platelets in the blood: fatigue, weakness, bleeding or bruising more easily than normal, nose bleeds		✔	
Decreased white blood cells: fatigue, fever, aches, pains, flu-like symptoms, sore throat, increased infections		✔	
Psychotic disorders: hallucinations (hearing and seeing things that are not there), psychosis aggression		✔	
Severe skin reactions (SJS, DRESS): sever skin peeling, scaling or blistering which may affect the mouth, eyes, nose or genitals, itching, severe rash, swelling and redness of the eyes or face, flu-like			✔

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
feeling, fever, chills, body aches, swollen lymph nodes, cough, yellow skin or eyes, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine			
Pain and inflammation of the joints		✔	
Porphyria (blood disease): abdominal pain, light sensitivity causing rashes, blistering or scaring of the skin, seizures, mental disturbances, nerve damage			✔
Ataxia: lack of voluntary coordination of muscle movements		✔	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store ZARONTIN / ZARONTIN SYRUP in a dry place at room temperature (15°C - 25°C) in the original packaging. Protect from light and freezing.

Keep out of reach and sight of children.

Do NOT keep outdated medicine or medicine no longer needed. Any outdated or unused medicine should be returned to your pharmacist.

If you want more information about ZARONTIN / ZARONTIN SYRUP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website https://www.searchlightpharma.com, or by calling 1-647-945-9762.

This leaflet was prepared by Searchlight Pharma Inc.

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