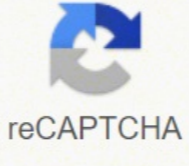




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The Pharmacokinetic Characteristics of Levetiracetam

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SUMMARY

Levetiracetam is the latest in a series of nine new antiepileptic drugs (AEDs) to be licensed for clinical use. Its parent license is for use as adjunctive therapy for the treatment of patients with partial seizures with or without secondary generalization that are refractory to other established first line AEDs. Pharmacokinetic studies of levetiracetam have been conducted in healthy volunteers, in patients of all ages with epilepsy, and in certain special populations. Results of these studies indicate that levetiracetam has a very favorable pharmacokinetic profile, characterized by excellent oral absorption and bioavailability (c. 95%) and a mean elimination half-life in adults, children and the elderly of 7, 6, and 10.5 h, respectively. Levetiracetam is not bound to plasma proteins and is not metabolized in the liver, so it is not expected to be associated with significant pharmacokinetic interactions. Indeed, to the best of the author's knowledge, no clinically relevant pharmacokinetic interactions with levetiracetam have yet been identified. However, pharmacodynamic interactions with carbamazepine and topiramate have been highlighted. As levetiracetam is primarily excreted unchanged in urine, dosage adjustments are necessary for patients with moderate-to-severe renal impairment. Overall, the pharmacokinetic characteristics of levetiracetam can be considered highly desirable. © 2003 Proton Science. All rights reserved.

Key words: Epilepsy - Levetiracetam - Pharmacokinetics

INTRODUCTION

Treatment of epilepsy with antiepileptic drugs (AEDs) invariably involves long-term treatment (usually years, decades or a lifetime), often with polytherapy (30% of patients with intractable epilepsy take 2 or more AEDs) and inevitably with other drug classes (for the treatment of nonepilepsy-related conditions). Consequently, the pharmacokinetic characteristics of AEDs are very important, particularly since this impacts on their efficacy and safety profile and also how the drug is prescribed, and consequently the acceptance of the drug by the patient. Indeed, the unfavorable pharmacokinetic characteristics of some currently available AEDs, as opposed to a lack of efficacy, has limited their widespread use.

During the past decade, numerous pharmacokinetic characteristics have been identified as being ideal in relation to AEDs, and these are summarized in Table 1 (1, 2). Compared with the long established AEDs (phenobarbital, primidone, phenytoin, carbamazepine and valproic acid), the new generation of AEDs (felbamate, gabapentin, lamotrigine, levetiracetam, tiagabine, topiramate, oxcarbazepine, vigabatrin and zonisamide) are clearly associated with significantly more desirable pharmacokinetic characteristics (3).

Levetiracetam (Keppra®) is the latest AED to be licensed for clinical use (3). It is licensed for use as adjunctive therapy for the treatment of patients with partial seizures with or without secondary generalization that are refractory to other established first line AEDs (4). However, there is increasing evidence that it is also effective in patients with generalized epilepsy (5, 6). Levetiracetam, (S)-4-ethyl-2-oxo-1-pyrrolidine acetamide (Fig. 1), is a pyridone derivative that has a similar chemical structure to numerous nootropic drugs and is the S-enantiomer of the ethyl analogue of piracetam (7). It is structurally unrelated to other AEDs and has unique preclinical and clinical profiles. Because levetiracetam is ineffective in the classical screening models for acute seizures, its antiepileptic efficacy was nearly overlooked. Its significant clinical efficacy and highly favorable therapeutic index is already establishing levetiracetam as a very useful AED (8-10).

This review summarizes the current understanding of the pharmacokinetic characteristics of levetiracetam in healthy volunteers, and in adults, children and elderly people with epilepsy, including patients with renal and hepatic impairment and those receiving concomitant medication with other AEDs or non-AED drugs.



How effective is 500 mg metformin. Can i buy metformin at walmart. Does 500mg of metformin work.

Talk to your health care provider to discuss treatment options if you are taking a recalled product or if you have taken a recalled product and are concerned about your health. Symptoms of high blood sugars include increased urination, thirst, excessive hunger, fatigue, blurred vision, drowsiness, irritability, unintended weight loss and dizziness. Very high blood sugars can lead to effects such as vomiting, diarrhea, dehydration, confusion, agitation and coma. Last updated: 2020-06-13 Product: Certain brands of diabetes drugs containing metformin, is recalling six lots of its prescription RAN-Metformin drug from the Canadian market. is voluntarily recalling nine additional lots of its prescription metformin drug, APO-METFORMIN ER (extended release) 500mg tablets. A person taking a drug that contains NDMA is not expected to have an increased risk of cancer. A healthcare professional should be consulted before taking any drug, changing any diet or commencing or discontinuing any course of treatment. The Department asked companies to test their metformin products and is conducting testing in its own laboratories, by calling toll-free at 1-866-840-1340, or by e-mail at canadacustomerservice@sunpharma.com JAMP Pharma by calling toll-free at 1 866-399-9092. If these symptoms occur, tell your doctor right away. Keep a list of all your medications with you, and share the list with your doctor and pharmacist. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. Individuals taking metformin, including a recalled product, should not stop taking it unless they have spoken to their health care provider as the risks from not having adequate diabetes treatment outweigh any possible effects of exposure to the levels of NDMA found in the recalled products. Company testing identified two lots (#AJY8006A and #AJY8007A) with levels of NDMA above what is considered acceptable if the drug were to be taken over a lifetime. There are alternative metformin products on the Canadian market manufactured by other companies. NDMA is not expected to cause harm when ingested at low levels. In December 2019, Health Canada communicated that it is assessing the issue of NDMA in metformin products, after some metformin products available outside Canada were detected to contain NDMA above the acceptable limit. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. If you don't have these reliable forms of glucose, rapidly raise your blood sugar by eating a quick source of sugar such as table sugar, honey, or candy, or drink fruit juice or non-diet soda. US residents can call their local poison control center at 1-800-222-1222. Health Canada has been working to address the issue of NDMA and other nitrosamine impurities found in certain medications since the summer of 2018. Side Effects Consult your pharmacist or physician in the US - Call your doctor for medical advice about side effects. Apotex Inc. Precautions Consult your pharmacist or physician. Please refer to the Affected products table below for detailed information on the recalled lots. NDMA test results are not available for this product; this recall has been initiated because of the potential presence of nitrosamine impurities in the finished product. CONDITIONS OF USE: The information in this database is intended to supplement, not substitute for, the expertise and judgment of healthcare professionals. NDMA is classified as a probable human carcinogen. The risks from not having adequate diabetes treatment outweigh any possible effects of exposure to the levels of NDMA found in the recalled products. Media enquiries Public enquiries Update: June 13, 2020 Apotex Inc. APO-METFORMIN ER (Metformin Hydrochloride Extended-Release Tablets) 02305062 500mg PK3968 09/2020 PK3969 09/2020 PX5336 01/2021 PY7174 02/2021 PY7175 01/2021 RF6463 06/2021 RF6464 06/2021 RF6465 06/2021 RF6466 06/2021 Related links Health Canada (613) 957-2983hc.media.sc@canada.ca Missed Dose Consult your pharmacist or physician. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: easy bleeding/bruising, signs of infection (such as persistent sore throat, fever), persistent nausea, severe stomach/abdominal pain, yellowing eyes/skin, dark urine. This medication can cause low blood sugar (hypoglycemia). What to do: You should not stop taking your metformin drug without first discussing options with your health care provider. Original Information Update: February 5, 2020 - Apotex Inc. You may report side effects to Health Canada at 1-866-234-2345. Talk to your health care provider to discuss treatment options if you are taking or have taken a recalled product and are concerned about your health. Health Canada is also working closely with international regulatory partners, including the U.S. Food and Drug Administration and the European Medicines Agency, to inform its assessment. As a precautionary measure, the company is also recalling eight other lots because levels of NDMA in those products may increase over time. Selected from data included with permission and copyrighted by First Databank, Inc. What consumers should do You should not stop taking your metformin drug without first discussing options with your health care provider. There are also alternative metformin products on the Canadian market manufactured by other companies. Health Canada continues to work closely with international regulatory partners to address the issue. APO-Metformin ER (Metformin Hydrochloride Extended-Release Tablets) 02305062 500 mg NV3244 04/2020 NV3245 04/2020 NV3246 04/2020 NV3247 04/2020 NV3248 04/2020 PX5334 01/2021 PX5335 01/2021 Ranbaxy Pharmaceuticals Canada Inc. Canada residents can call a provincial poison control center. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. In Canada - Call your doctor for medical advice about side effects. Affected products The following is a list of metformin drugs being recalled in Canada at this time: Company Product Name/Active Pharmaceutical Ingredient (API) DIN Strength Lot Expiry Apotex Inc. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Apotex Inc. This may occur if you do not consume enough calories from food or if you do unusually heavy exercise. These include heart disease, nerve problems, kidney damage, blindness and amputations. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. It is a good habit to carry glucose tablets or gel to treat low blood sugar. Company test results showed one of the lots (PY7174) contains a nitrosamine impurity called N-nitrosodimethylamine (NDMA) that increased over time to a level above the acceptable limit. Ranbaxy Pharmaceuticals Canada Inc. UPDATE: March 11, 2020 JAMP Pharma Corporation is voluntarily recalling all 26 lots of its prescription Metformin drug from the Canadian market (Metformin DIN 02380196 [500mg] and Metformin DIN 02380218 [850mg]) as a precautionary measure. Symptoms of low blood sugar include sudden sweating, shaking, fast heartbeat, hunger, blurred vision, dizziness, or tingling hands/feet. Report any health product adverse events or complaints to Health Canada. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for you or anyone else. Metformin is a prescription drug used to control high blood sugar in patients with type 2 diabetes. Health Canada continues to assess this issue, and will update the table below and inform Canadians should any additional recalls be necessary. The Department will take action if a new risk to Canadians is identified, and will continue to inform the public of new safety information. Stopping metformin medication could lead to uncontrolled diabetes, which can cause serious health problems such as: High blood sugars. This copyrighted material has been downloaded from a licensed data provider and is not for distribution, except as may be authorized by the applicable terms of use. RAN-Metformin 02269031 500 mg AJY8006A 05/2020 500 mg AJY8007A 05/2020 500 mg AJY8005A 05/2020 500 mg AJY8005B 05/2020 500 mg AJY8008A 05/2020 850 mg AJZ8005A 05/2020 JAMP Pharma Metformin 02380196 500 mg X20283 11/2020 X20284 11/2020 X20286 11/2020 X20287 11/2020 X20288 11/2020 Y00225 12/2020 Y00226 12/2020 Y00227 12/2020 Y00228 01/2021 Y00229 01/2021 Y00230 01/2021 Y00231 05/2021 Y00232 05/2021 Y01573 05/2021 Y01574 05/2021 Y01575 05/2021 Y01576 05/2021 Y01577 05/2021 Y01578 05/2021 Y01579 06/2021 Y01580 06/2021 02380218 850 mg X20385 07/2020 X20386 07/2020 X19224 10/2020 X19225 10/2020 X19226 10/2020 Apotex Inc. recalls certain lots of the diabetes medication APO-Metformin ER (extended release) 500 mg tablets You should not stop taking your medication without first discussing treatment options with your health care provider. Issue: Products contain or may contain a nitrosamine impurity, N-nitrosodimethylamine (NDMA), above or close to the acceptable limit. We are all exposed to low levels of nitrosamines through a variety of foods (such as smoked and cured meats, dairy products and vegetables), drinking water and air pollution. Check with your doctor or pharmacist to find out what you should do if you miss a meal. Symptoms of high blood sugar (hyperglycemia) include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, and fruity breath odor. Who is affected Patients who are taking an affected metformin drug. UPDATE: February 26, 2020 Ranbaxy Pharmaceuticals Canada Inc. has tested all lots of its 500 mg extended release tablets; only the affected lots are being recalled (see table below). If stomach symptoms return later (after you are on the same dose for several days or weeks), tell your doctor right away. is recalling eight lots of its 500 mg extended release metformin tablets (APO-Metformin ER) because they contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA) above the acceptable limit. Contact the company directly if you have questions about a recall: Apotex Inc. via Stericycle ULC by calling toll-free at 1-855-853-9461. Stomach symptoms that occur after the first days of your treatment may be a sign of lactic acidosis. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. The risks from not having adequate diabetes treatment outweigh any possible effects of exposure to the levels of nitrosamines found in the recalled Apotex metformin products. Longer-term health impacts. The company is recalling an additional four lots (#AJY8005A, #AJY8005B, #AJY8008A and #AJZ8005A) as a precautionary measure because they contain NDMA close to the acceptable limit. In Canada - Call your doctor for medical advice about side effects. See also Warning section. Nausea, stomach upset, diarrhea, or weight gain may occur. recalls certain lots of the diabetes medication APO-Metformin ER (extended release) 500 mg tablets Issue Apotex Inc. You may report side effects to Health Canada at 1-866-234-2345. Page 2 Uses Consult your pharmacist or physician. Ask your pharmacist if you are unsure whether you are taking a recalled product. Notes No monograph available at this time. Interactions Consult your pharmacist or physician. Tell your doctor right away about the reaction and the use of this product. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. Otherwise, call a poison control center right away. Should any additional recalls be necessary, Health Canada will update the table below and inform Canadians. Your dosage may need to be increased. A very serious allergic reaction to this drug is rare. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects.

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