

## Use of Axen Forte (Asfarma, Turkey) in Diabetic Adolescents with Neuropathic Symptoms

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### ABSTRACT

Efficacy of non-steroidal anti-inflammatory drugs in different systemic diseases of connective tissue, as well as in diabetic neuropathic symptoms, is well established. However, there is little data regarding the use of axen forte (naproxen sodium, 550 mg) in diabetic patients with above complications to relieve the neuropathic symptoms (paresthesia, pain, burning, numbness) in lower extremities. Our aim was to evaluate the efficacy and safety of axen forte in adolescents with diabetes type I, which developed neuropathic symptoms of different (from mild to moderate) severity. For this purpose, we performed clinical and electrophysiologic study of 12 adolescents (16 - 18 y) with newly diagnosed (within 10 days) and long duration (up to 10 years) poorly controlled diabetes, which developed neuropathic symptoms. A control group included 12 adolescents of the same age, duration and severity of diabetes and similar clinical symptoms. After administration of axen forte (275 mg/day) in patients from main group, the intensity and frequency of above neuropathic symptoms were considerably reduced compared to age-matched control subjects. None of patients did show side effects of pharmacological treatment. These data show efficacy of axen forte in diabetic neuropathy.

**KEYWORDS:** neuropathic symptoms, diabetic neuropathy, non-steroidal antiinflammatory drugs, nerve conduction study

**A**xen forte (naproxen sodium, 550 mg) is a non-steroidal anti-inflammatory drug, which is used in pediatric practice for systemic diseases of connective tissue, and also in adults with different neurological disorders, such as radiculopathy, postherpetic neuralgia, muscle contraction headache, migraine and others [1,2].

There is data [3] regarding the use of some non-steroidal drug such as indomethacine and aspirin in patients to relieve the neuropathic symptoms (paresthesia, pain, burning, numbness) in lower extremities, however, there is no data concerning the use of axen forte in those disorders.

There is also well-established data [4] concerning the efficacy of some anti-epileptic drugs, such as phenytoin, neurontin (gabapentine), carbamazepine and also opiates (tramadol) in adults with painful diabetic neuropathy; however, the use of above drugs in pediatric practice is strictly limited because of prominent side effects.

According to the above-mentioned, it was our aim to evaluate the efficacy and safety of axen forte in adolescents with different duration of diabetes, which developed the above-mentioned symptoms of diabetic peripheral neuropathy from mild to moderate severity.

### MATERIALS AND METHODS

We have studied clinically and by electrophysiologic method (electroneurography) 16 to 18 years old 24 adolescents (10 girls) with diabetes type I. Main group included 12 patients with the following duration of disease: in 2 patients diabetes was newly (within 10-14 days) diagnosed, in 4 patients duration of diabetes was about 2-3 years and in 7 patients diabetes duration was 8-10 years. A control group included 12 adolescents with the same age, duration of diabetes and with similar clinical symptoms. Diabetes control was evaluated by glycosylated hemoglobin (HbA1c%), which showed poorly controlled diabetes ( $HbA1c=14.2\pm 2.6\%$ ,  $p<0.001$ ) in all patients ( $n=24$ ). Electrophysiologic study was performed by Medelec Mystro MS 20 electromyograph and

included testing of peroneal and tibial motor nerve conduction velocities (NCVs), as well as study of sural NCV and sural sensory nerve action potential (SNAP) amplitudes.

Evaluation of diabetic peripheral neuropathy symptoms was based on Apfel and colleagues' scheme (1999) and included detection of paresthesias, pain, burning and numbness in patients' lower extremities [5]. The frequency and intensity of neuropathic symptoms was detected by Ziegler and colleagues' (1995) total symptom score [6]. The study was done in Pediatric Clinic of Tbilisi State Medical University and during the period from November 2003 to October 2004.

### RESULTS

In 18 patients included both in main and control groups electrophysiologic studies showed abnormally slow motor and sensory NCVs, as well as markedly reduced sural SNAP amplitudes. Those data were matched with the clinical symptoms of painful diabetic peripheral neuropathy in lower extremities. In the main group of adolescents ( $n=12$ ) we used axen forte 275 mg/day within 5 to 7 days of period. In addition, the strict metabolic control was administered.

After the above period of treatment in those patients we observed considerable reduction of neuropathic symptoms compared to the age-matched control subjects who did not receive pharmacological treatment. In 9 patients (from the main group) we observed complete diminished of pain and paresthesia. And in 3 patients with diabetes duration of 8-10 years, the intensity and frequency of above-mentioned neuropathic symptoms were considerably reduced.

Besides, we observed considerably improved electrophysiologic data in adolescents receiving axen forte (275 mg/day) after NCS was performed again within 3 months of strict metabolic control. This time we revealed considerably improved motor and sensory NCVs and sural SNAP amplitudes in those patients. It should be emphasized that none of our patients did reveal any side effect of axen forte.

**CONCLUSION**

Our study has shown that axen forte is safe and effective in neuropathic symptoms expressed with different severity in adolescents with diabetes type I.

It is important to mention, that improvement of such complications of diabetes can be achieved with a short (within several days) course of treatment with axen forte.

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## Применение препарата Ахен Форте (Асфарма, Турция) у подростков с симптомами диабетической нейропатии

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### Р Е З Ю М Е

Препарат ахен форте (напроксен натрия, 550 мг) является нестероидным противовоспалительным медикаментом, который применяется в педиатрии, а также в неврологии для купирования боли при мигрени и радикулопатии. Для определения эффективности ахен форте 12 подростков (16 - 18 л) больные диабетом I типа с нейропатическими симптомами (боль и парестезия в нижних конечностях) получали данный препарат в день 275 мг в течение 5 - 7 дней. Электрофизиологические показатели (определение скорости проведения нервного импульса по периферическим моторным и сенсорным нервам) соответствовали нейропатическим симптомам. После назначения ахен форте и строгого метаболического контроля вышеуказанные симптомы исчезли. Также наблюдалось заметное улучшение скорости проведения нервного импульса. Наше обследование указывает на эффективность и безопасность ахен форте при нейропатических симптомах у больных сахарным диабетом.

**Ключевые слова:** *нейропатические симптомы, диабетическая нейропатия, нестероидные противовоспалительные лекарства, изучение нервной проводимости*