Дженерики при лечении ожирения

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Ревоме. У Меридиа" и Ксеникала" существует несколько псевдодженериков. Зарегистрированный в России дженерик Меридиа" — Линдакса" вполне может проигрывать бренду по соотношению «цена/качество». Кноченые слова: дженерики, ожирение.

Resume. There are several pseudogenerics of Meridia* and Xenical*. Lindaua*, registered in Russia, as a generic of Meridia*, can be at a disadvantage to a brand on cost—quality ratio. Key words: generics, obesity:

оспроизведенные препараты - дженерики (от англ. generic - калька) все чаще используются в практике заравоохранения при дечении различных заболеваний, включая ожирение. Однако очень релко проблемы, связанные с применением этих лекарственных средств, находят свое отражение в мелицинской печати. Привелем лиць одинпример. Поиск в общириейшей Национальной базе данных медико-биологических pecypeon CIIIA (http://www.ncbi.nlm.nih.gov/PubMed) aan seero 8 ccssлок на публикации, в пределах которых где-либо (заглавии, резюме или тексте) встречаются два термина: «дженерики» и «ожирение». Оченидно, что столь скудная информация не предоставляет возможности для полношенного анализа проблемы. В связя с этим представляется целесообразным в настоящей статье рассмотреть более широкий круг публикаций, свилетельствующих как в пользу использования дженериков, так и против применения этих препаратов в клиническоой практиве...

Основные аргументы за назначение воспроизведенных препаратов выглядят следующим образом. Указывается, что дженерик полностью соответствует (эжинвалентен) своему оригиналу - бренду (от англ. brand - торговая марка). Причем эквивалентность указаянных препаратов прослеживается на фармацевтическом, фармакокинетическом и терапевтическом уровнях (т.н. фармацентическая, фармакокинетическая и терапевтическая эквивалентность соответственно) [11]. Это означает, что оригинальное и воспроизведенное лекарственное средство содержит одни и те же активные (действующие) субстанции в одинаковом количестве и форме — фармацентическая эквивалентность (допускаются лишь отличия по использованным наполнителям, красителям, особенностям покрытия). Фармакокинетическая эквивалентность (или биоэквивалентность) подразумевает, что скорость и степень всасывания дженериков (предназначенных для приема внутрь, накожной аппликации, ректального введения, при условии, что их действие опосредовано появлением действующего вещества в системном кровотоке) и их брендов после введения в одинаковой молярной

дозе сходня до такой степени, что эффективность и безопасность упомянутых препаратов не могут не быть одинаковы [3]. Наконец, оригинальное и воспроизведенное лекарственные средства полностью сопоставимы по параметрам эффективности и безопасности, полученным в ходе клинических исследований (терапевтическая эквивалентность).

При эквивалентности бренда и дженерика последний отличает более низкая стоимость (фармакоэкономичесое преимущество) [17, 29]. В результате нередко полчеркивают, что воспроизведенные препараты снижают прямые затраты на лечение, содействуют развитию конкурентной борьбы и снижению цен на оригинальные лекарственные средства и даже являются одним из способов висдрения экономическо эффективных медицииских технологий в кливическую практику [9].

Очевилно, что все представленные аргументы звучат чрезвычайно убедительно. Однако вплоть до настояшего времени появляются публикации, в которых выражаются те или иные сомнения в целесообразности использования дженериков. Сощлемся на сравнительно недавно появившийся систематический обзори метавиализ американских исследователей из Бостона. [19]. В этой работе авторы, в частности, изучили 43 редакционных статые относительно целесообразности замены брендов, использующихся при дечении серлечно-сосущистой латолютии. 31636 Указывается, что 23 (53%) из них содержат отрицательную оценку перехода с брендовых препаратов на джеисриковкас.

Другой пример — исследование, охватившее Германию, Великобританию, Испанию, Канаду, Францию, в ходе которого был проведен опрос миений основных участников лечебного процесса (больные и их врачи) относительно воспроизведенных препаратов [16]. При этом установлено, что большинство пациентов сомневаются в переносимости дженериков (66%), их эффективности (69%) и согласны с утверждением о том, что даже небольшие биохимические отличия между брендовыми и дженериковами лекарственными средтевами могут существенным образом сказаться на результатах лечения и его эффективности (88%).

Patrick Vollmar

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- 1. Understanding the eBook Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - o The Rise of Digital Reading Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Advantages of eBooks Over Traditional Books
- 2. Identifying Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
- 3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - o Features to Look for in an Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - User-Friendly Interface
- 4. Exploring eBook Recommendations from Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Personalized Recommendations
 - o Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma User Reviews and Ratings
 - Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma and Bestseller Lists
- 5. Accessing Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma Free and Paid eBooks
 - Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma Public Domain eBooks
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 - o Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma Budget-Friendly Options

- 6. Navigating Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma eBook Formats
 - o ePub, PDF, MOBI, and More
 - Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma Compatibility with Devices
 - Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Highlighting and Note-Taking Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - o Interactive Elements Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
- 8. Staying Engaged with Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
- 9. Balancing eBooks and Physical Books Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - o Setting Reading Goals Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma
 - Fact-Checking eBook Content of Ekstrakorporalnaia I Intrakorporalnaia Gemokorrektsiia Pri Lechenii Krashsindroma

- Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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