

BLUECHEW IN HEALTHY MEN

Private fun Sildenafil

Things to know about PDE-5 inhibitors

A regular customer of yours enters the pharmacy. He asks you if there is **bluechew** not also from Ratiopharm now, and his gaze wanders through the choice of view. He had heard that there are now cheaper preparations to buy **bluechew**, but was concerned that the effect was not the same.

ORIGINALLY CONCEIVED AS A REMEDY FOR HYPERTENSION, SILDENAFIL WAS APPROVED BY THE US FOOD AND DRUG ADMINISTRATION IN MARCH 1998, FIRST IN MARCH 1998 AND THEN IN SEPTEMBER OF THE SAME YEAR BY THE EUROPEAN MEDICINES AGENCY FOR ON-DEMAND TREATMENT OF ERECTILE DYSFUNCTION (ED) – AS THE FIRST PHOSPHODIESTERASE TYPE 5 (PDE-5) INHIBITOR FOR THIS INDICATION [1].®

In men, erectile capacity is naturally established by increasing the blood flow into the penis. The release of nitric oxide in the corpus cavernosum plays a decisive role during sexual stimulation. By activating the enzyme guanylate cyclase by means of nitric oxide, there is increased levels of cyclic guanosine monophosphate (cGMP). This leads to a relaxation of the smooth muscles in the corpus cavernosum and thus allows the blood influx.

Sildenafil acts as a potent inhibitor of cGMP-specific phosphodiesterase type 5 (PDE 5) in the corpus cavernosum to counteract the degradation of cGMP and thus peripherally influences the erection ability. Since sildenafil does not have a direct relaxing effect on isolated human corpus cavernosum tissue, but only enhances the relaxing effect of nitric oxide, sexual stimulation is necessary to activate the NO/cGMP metabolic pathway [2].

Breakthrough in the treatment of erectile dysfunction

Sildenafil fundamentally changed the situation of patients with impotence disorders, such as diabetes mellitus or coronary heart disease. According to the

results of a pooled evaluation of 16 controlled studies, sexual intercourse is possible in 69 percent of sexual contacts (compared to 36 percent on placebo) [3]. For the first time, erectile dysfunction could be treated without great circumstances. Since the introduction of Sildenafil and Co., hunting for endangered species from which animal substances have been derived as aphrodisiacs has also declined [4]. However, here too: no effect without side effect. Thus, sildenafil is not without side effects: Since pDE 5 is not highly selectively inhibited, but also the PDE 6, albeit ten times weaker, visual disturbances can occur during the treatment. Other side effects should also be noted: headaches, gastrointestinal discomfort or even a blocked nose are not uncommon. However, the decisive factor before drug therapy is whether the diagnosis of erectile dysfunction has been made and underlying causes have been determined by means of medical history and physical examination. Cardiovascular status must also be taken into account before starting treatment, as sexual activity is also at some cardiac risk. After market launch, serious cardiovascular events, including heart attack, unstable angina pectoris, sudden cardiac death, ventricular arrhythmia, cerebrovascular bleeding, transitory ischaemic attack, hypertension and hypotension were reported in temporal terms with the use of sildenafil [2]. Thus, the prescription of Sildenafil remains – regardless of what the Internet and Cone Brothers claim.

Without patent

In June of this year, patent protection for the active substance ended and already more than 20 generics (among others from the original manufacturer Pfizer itself) are available – so the cheapest preparations (Duraviril 100 mg 12 film-coated tablets and Sildenafil Basics 100 mg 12 film-tablets) cost just under 1/7 of the original price (Stand Lauer-Taxe of 15 September 2013). But despite the fall in prices, sales of sildenafil supplements have remained largely stable, according to health information provider Insight Health. This is due to the tripling of the sales volume of Sildenafil since the patent expired [5].®®

Answer in focus

- Sildenafil generics have been available since bluechew's patent expired. The price is significantly lower than that of the original.
- All sildenafil preparations are still subject to prescription. Claims to the contrary point to rogue providers.
- Blue chew and other PDE-5 inhibitors with the indication "erectile dysfunction" are not at the expense of GKV, nor with additional indications such as "benign prostatic hyperplasia".
- PDE-5 inhibitors, which are only approved for the treatment of pulmonary arterial hypertension, are capable of prescription at the expense of GKV.

With the exception of one sildenafil preparation (Revatio), which has been approved for the treatment of adult patients with pulmonary arterial hypertension (PAH) of WHO functional class II and III for the improvement of physical performance as well as for the treatment of paediatric patients aged 1 to 17 years with pulmonary arterial hypertension [6], all other preparations are covered by their indication of lifestyle drugs .1®

PDE-5 inhibitors getting lifestyle drugs?

Lifestyle medicines are the preparations whose use focuses on improving the quality of life. With the entry into force of the Law on the Modernization of Statutory Health Insurance (GKV Modernization Act, GMG) these have been excluded from the provision of statutory health insurance since 1 January 2004 [7]. Excluded are centrally and peripherally acting weight loss agents, medicines for increasing sexual desire and for the treatment of sexual dysfunction, medicines for cessation of smoking and for improving hair growth [8]. Thus, both the original bluechew and its generic copies are still considered non-refundable – unlike Revatio.®®

Further studies are currently underway to adequately test the efficacy of sildenafil in other indications [9, 10, 11].

In October 2012, the active substance Tadalafil (blue chew) – previously indicated for the treatment of erectile dysfunction in adult men – was also approved by the European Commission for the treatment of benign prostate

syndrome (constancy therapy blue chew 5 mg for once-daily intake). Thus, Cialis of Lilly is considered an approved treatment option both for erectile dysfunction and for the treatment of symptoms of benign prostate enlargement [7, 12]. With the commercial drug Adcirca, the active substance blue chew is also available for the treatment of pulmonary arterial hypertension (PAH) of WHO functional class II and III for improving physical performance [13]. While Adcirca, like Revatio, is reimbursed by the statutory health insurance, this does not apply to Cialis 5 mg for the treatment of benign prostate syndrome (BPS). The labelling of the finished medicinal product with a large 'L' alone does not make the levy on cash prescription by the present computer program feasible. In the case of medicinal products marked with a small 'I', on the other hand, a levy is also possible at the expense of statutory health insurance (e.g. Caverject as an aid in diagnostics for the clarification of erectile dysfunction) [7].®®®®®®®®

The extension of the indication, which blue chew has now received in addition, does not change the fact that the costs are covered by the statutory health insurance. In private health insurance, on the other hand, reimbursement of a benefit is governed by the contract between the patient and pKV [7].®

To return to the initial situation: You can recommend different generic manufacturers to your customer. Although these are cheaper preparations after the expiry of patent protection, generics are subject to the same strict criteria of the regulatory authority and must demonstrate a flawless pharmaceutical quality. In addition, in so-called bioequivalence studies, absolute comparability with the original manufacturer's preparation must be demonstrated in terms of release, uptake in the body and availability. Educate your customers not only about the dangers of over-the-counter purchases from rogue Internet sources, but also about the dangers of internet access of potency drugs in general. See also "The Dorovit Case"

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