



The European Agency for the Evaluation of Medicinal Products

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PUBLIC STATEMENT

EMEA Opinions on Sildenafil Citrate (Viagra)

Given the extent of media enquiries, and the level of reported information which may cause confusion to both patients and health professionals, the EMEA has decided to make the following public statement:

The CPMP, at its meeting of the 25–27 May 1998, adopted a positive opinion on a marketing authorisation application from Pfizer Limited UK for a medicinal product (Viagra) containing the new active substance, sildenafil citrate, for use in the treatment of erectile dysfunction. A positive opinion was also adopted on a second marketing authorisation application for an identical medicinal product submitted by Roerig Farmaceutici SpA. Pfizer Limited UK and Roerig Farmaceutici SpA are both wholly owned members of the Pfizer Group of companies.

It is emphasised that neither medicinal product is at the present time authorised to be placed on the market in the European Union (EU).

The EMEA positive opinions will now be transmitted to the European Commission and all EU Member States. The decision whether to grant marketing authorisations for these products will be taken by the European Commission after consultation with the Member States. This decision-making phase generally takes 3 months to complete.

Once the European Commission has granted the marketing authorisations, the European public assessment reports (EPAR) will be made available on the EMEA website (<http://www.eudra.org/emea.html>). Along with the scientific assessment report detailing the reasons for the EMEA opinions, the EPAR also includes the full information for health professionals ('summary of product characteristics') and for patients ('patient information leaflet'). The following information is based on the current versions of the summary of product characteristics and patient information leaflet.

Sildenafil is indicated for the treatment of erectile dysfunction, which is the inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. In order for sildenafil to be effective, sexual stimulation is required.

Sildenafil will be available only on medical prescription. It is indicated for use in men over 18 years of age who have undergone a medical history and physical examination by a physician to diagnose erectile dysfunction, determine any potential underlying causes and decide if pharmacological treatment is appropriate. Prior to initiating any treatment for erectile dysfunction physicians should consider the cardiovascular status of their patients.

Sildenafil is not indicated for use by women.

Patients should not be prescribed sildenafil if they are taking nitrates, which are often for the relief of angina pectoris, or nitric oxide donors, e.g. amyl nitrite ('poppers'). Similarly patients should not be prescribed sildenafil if they have recently had a stroke or a heart attack, have low blood pressure, severe heart or liver problems, or certain rare inherited eye diseases (such as retinitis pigmentosa).

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In addition, caution should be exercised before prescribing sildenafil for patients with sickle cell anaemia (abnormal red blood cells), leukaemia (cancer of blood cells), multiple myeloma (bone marrow cancer), bleeding disorders, active peptic ulceration, or any disease or deformity of the penis.

Sildenafil must not be used together with other treatments for erectile dysfunction.

In addition to evaluating the data presented in the marketing authorisation applications, in reaching its opinions the CPMP also considered the latest safety data available (including information presented by the applicants on deaths reported to them) from patient experience in the United States. In view of the magnitude and rate of increase of patient experience in those countries where the products are already authorised and marketed, the CPMP requested that until EU authorisations are granted, the applicants will provide the EMEA with frequent updates on the use of sildenafil, including comprehensive reports of adverse reactions received in that period. Once authorisations are granted, the safety profile of the products will continue to be reviewed intensively by the EMEA.

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For further information contact

Prof. Rolf Bass
Head of Unit for Human Medicines
Tel: +44.171.418.8411
Fax: +44.171.418.8551

NOTES FOR EDITORS

1. The European Agency for the Evaluation of Medicinal Products (EMEA) was created in 1995 for the scientific evaluation, and subsequent monitoring, of applications for biotechnology and other high technology medicinal products for human and veterinary use. It also arbitrates where Member States are unable to mutually recognise national marketing authorisations for other medicines.
2. The Committee for Proprietary Medicinal Products (CPMP) is the scientific committee of the EMEA responsible for the evaluation of medicines for human use.
3. A Community marketing authorisation granted by the European Commission, following an EMEA opinion, is valid throughout all EU Member States.
4. As announced in May 1998, the draft Package Leaflet (Viagra 25 mg, as relevant example) in all 11 official EU languages is now available from the EMEA Website on the Internet. This patient information represents the latest draft version under review in the Commission decision-making procedure. The Commission decision on Marketing Authorisation is normally expected for September 1998 at which time the final text will be made available as part of the full European Public Assessment Report (EPAR).