

Department of Health, Social Services & Public Safety
An Roinn Sláinte, Seirbhísí Sóisialta agus Sábháilteacht Phoiblí

From The Chief Medical Officer:
Dr Henrietta Campbell CB

Castle Buildings
Upper Newtownards Road
Belfast BT4 3SJ

Telephone: 028 90520563
Fax: 028 90520574

E-Mail: henrietta.campbell@dhsspsni.gov.uk

URGENT COMMUNICATION

HSS (MD) 18/2000

Directors of Public Health
GP Advisers
All GPs
Chief Executives of HSS Boards
Chief Executives of HSS Trusts
Medical Directors of HSS Trusts for onward
Casade to all consultants
Directors of Nursing HSS Boards & Trusts

20 July 2000

Dear Colleague

SUSPENSION OF CISAPRIDE (PREPULSID) LICENCES: PRODUCT WITHDRAWAL

Please find enclosed information published by the Committee on Safety of Medicines relating to the withdrawal of CISAPRIDE (PREPULSID). The following information is attached:

Message from Professor A Breckenridge, Chairman, Committee on Safety of Medicines

Information for people taking Cisapride (Prepulsid)

Yours sincerely



PAUL DARRAGH (Dr)
Deputy Chief Medical Officer

cc Miss Hill, CNO



INVESTOR IN PEOPLE

MESSAGE FROM PROFESSOR ALASDAIR BRECKENRIDGE, CHAIRMAN,
COMMITTEE ON SAFETY OF MEDICINES

20 July 2000

CEM/CMO/2000/9

Suspension of cisapride (Prepulsid) licences: Product withdrawal

Dear Health Professional

I am writing to inform you that cisapride (Prepulsid) will be withdrawn from marketing in the UK from 28 July 2000 until further notice. The Committee on Safety of Medicines (CSM) has advised that all treatment with cisapride should be stopped and patients should be changed to alternative treatment as necessary. No particular precautions are required when cisapride is stopped. An information sheet for patients is attached.

Cisapride, a gastrointestinal motility stimulant was licensed for the treatment of adults with gastro-oesophageal reflux, non-ulcer dyspepsia or impaired gastric emptying. It has never been licensed for use in children. However, unlicensed use in children has occurred and should also stop.

Cisapride can prolong the QT interval, which may lead to rare but life-threatening ventricular arrhythmias. Since 1988 when cisapride was authorised in the UK, the Yellow Card Scheme has received 60 reports from the UK of serious cardiovascular reactions, 5 of which were fatal. World-wide there have been 386 reports of serious ventricular arrhythmias (125 fatal) suspected to be due to cisapride therapy, and 50 reports of sudden unexplained death. The extensive usage of cisapride confirms that these reactions are rare.

The risk of arrhythmias with cisapride is increased by certain underlying medical conditions, as well as concomitant use of medicines that prolong the QT interval, inhibit the metabolism of cisapride or produce electrolyte imbalance. These risk factors can be identified in many but not all of the reported cases. Previous action by the CSM has only had a limited effect in reducing co-prescribing of cisapride with contraindicated medication. Serious cardiovascular reactions, including fatalities continue to be reported.

The CSM has therefore advised that the benefits of cisapride are outweighed by the risks and that the product licences should be suspended. This will result in the withdrawal of cisapride from 28 July 2000 until further notice.

Concern about cardiac arrhythmias has recently led to the initiation of a European review of the risks and benefits of cisapride. This review will be considering what indications for cisapride, if any are justified and should be completed in 2001. The suspension of licences in the UK will be reassessed once this review has been completed.

For further information call:

Medicines Control Agency on 020 7273 0000,
or Janssen-Cilag (the manufacturer) on 0800 1697681.

Yours sincerely,

Prof Alasdair Breckenridge
Chairman, Committee on Safety of Medicines

INFORMATION FOR PEOPLE TAKING CISAPRIDE (PREPULSID)

Advice from the Medicines Control Agency

From 28 July 2000, the medicine cisapride (also known as Prepulsid) will be withdrawn from the UK market because of safety concerns. You therefore need to stop taking it and see your doctor to discuss alternative treatment.

What is cisapride?

Cisapride is a medicine that stimulates muscle contraction in the stomach, and is used to treat indigestion and other related symptoms.

Why will it no longer be available?

Abnormal heart rhythms are a very rare side effects of cisapride. These abnormal heart rhythms only affect a very small number of patients but may be serious. The type of abnormal heart rhythm caused by cisapride could result in episodes of palpitations, breathlessness or fainting.

Who has decided it should no longer be available?

Evidence relating to the side-effects of cisapride has been reviewed by the Committee on Safety of Medicines (an expert body that advises the government on medicines). This Committee has advised that cisapride should be withdrawn pending a European-wide review of its safety and benefits.

Are there any long-term effects?

No, there are no long-term effects on the heart; abnormal heart rhythms due to cisapride only occur while it is being taken.

Is it safe to stop cisapride straight away?

Yes, stopping cisapride does not carry any risks and the only likely effect is that symptoms such as indigestion might recur.

Are alternative treatments available and do they affect the heart?

Other medicines for digestive problems are available that do not cause abnormal heart rhythms. Please discuss this with your doctor or pharmacist.

How can I get further information?

For further information call:

NHS Direct on 08 45 46 47,

or Janssen-Cilag (the manufacturer) on 0800 1697681.