

Pill under review over link to depression

Pill linked to depression under review

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A brand of the contraceptive pill which is commonly prescribed to treat acne is under review by the UK's regulatory body amid concerns about the side-effects it has on young women.

The Medicines and Healthcare Products Regulatory Authority (MHRA) which licenses drugs is reviewing Dianette following the submission of a dossier from the charity April (Adverse Psychiatric Reactions Information Link). It has sent reports from more than 100 women who say they have plunged into serious depression while on the drug. Some of them have been on the drug for years, even though Dianette is only supposed to be prescribed for a short period.

Dianette is licensed as a hormone treatment for severe acne. It is an effective contraceptive, but doctors have been warned that they should not prescribe it solely for that purpose because it has a higher risk of blood clots than other similar combination pills. Women who take it are supposed to stop within three or four months of their skin problems clearing up.

Many who have contacted April claim the drug has severely affected their lives. Some say they have been prescribed antidepressants by their doctors, who have not suggested there could be any problem with Dianette, even though the manufacturer's information leaflet says one possible side-effect is "mild depression".

One who took Dianette for eight years said: "My depression was very bad and I have been deeply suicidal ... I can't tell you the difference in my depression almost within one week of coming off the tablets. I had gone from someone barely able to function because of my depression to actually looking forward to a new day."

Another said she had not been warned of potential side-effects. "I was put on Dianette when I was 15 as I had problems with acne," she wrote. "I am now 27 and continued to use Dianette as a contraceptive as my doctor told me that it was ok to do so. When I went to the doctor with severe panic attacks, I was prescribed beta blockers and Prozac which I took for two and a half years. I never linked Dianette with anxiety until I had a break from the tablets for three months. I noticed that my anxiety had dramatically subsided."

Millie Kieve, who runs the charity, says that labelling depression as "mild" sends the wrong signal. "It is not mild - it is serious," she said. "The doctor should warn these girls that if they are depressed, it could be Dianette, instead of putting them on antidepressants."

Young women were being labelled mentally ill when they were suffering side-effects from a medicine, she said. "We need a climate where people are looking at possible adverse drug

reactions instead of possible disease. They are only treating the symptoms - not looking for the cause."

The MHRA is particularly concerned by evidence that doctors are prescribing the drug as a contraceptive in spite of warnings. In an email to Ms Kieve, Jane Woolley of the pharmacovigilance risk assessment group said: "The MHRA shares your concerns over the prescribing of Dianette solely for contraception and has taken several steps in recent years to try to minimise this."

Information about the drug in the British National Formulary, the prescribers' bible, reminds doctors that it is only for severe acne in cases where oral antibiotics do not work. It also points to the increased risk over other pills of blood clots.

But Ms Kieve says the reports from women who have contacted her suggest that "there are doctors who do not read the warnings". She urged any women who had suffered from depression which they felt could be linked to Dianette to report the suspected side-effect through the MHRA's "yellow card" scheme (www.yellowcard.gov.uk).

The MHRA confirmed that its review was looking at the reports submitted by April on depression and also at data from the manufacturer. It said it hoped the findings would go to its expert advisory group on medicines for women's health at the end of May.

In March, after the review began, the MHRA granted a licence to an identical pill called Clairette. The authority says, however, that since Dianette had not been removed from the market, there was no reason not to grant the licence.

"Depression is a known adverse reaction of Dianette," it said in a statement. "The fact that the current wording in the patient information leaflet of the brand leader is being reconsidered on the basis of patient reports submitted by Ms Kieve and data from the MHRA was not felt to impact sufficiently on the balance of risks and benefits of the product to stop the licensing of a similar generic product. Any changes to the brand leader will be reflected in the generic products."

A spokeswoman for Schering Health Care, which manufactures Dianette, said: "We have not been informed by the MHRA of any review of Dianette. We do of course liaise closely and cooperate fully with the MHRA on all matters of patient safety."