

**Guidance on
the use of
paclitaxel in the
treatment of
ovarian cancer**

Date January 2003

Note This information replaces the patient leaflet on taxanes for ovarian cancer issued in May 2000

NICE website or from the NHS Response Line (for topotecan, quote N0020 for the full guidance and N0022 for information for patients; for PLDH, quote N0114 for the full guidance and N0116 for the information for patients).

If you have access to the Internet, you can find more information about ovarian cancer on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 08 45 46 47.

This leaflet is also available in Welsh, (Ref no. N0188).

Mae'r daflen hon hefyd ar gael yn Gymraeg (rhif cyfeirnod N0188).

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What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance for both the NHS and patients on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures and under what circumstances they should be used.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance. Each appraisal takes about 12 months to complete.

In May 2000, NICE issued guidance to the NHS in England and Wales on the use of paclitaxel for the treatment of ovarian cancer. NICE always reviews its guidance taking into account any new evidence. Following a review, NICE has updated its guidance on paclitaxel for the treatment of

ovarian cancer. This new guidance was published in January 2003.

Cancer is a disease of the body's cells. Normally, all cells divide and reproduce themselves in an orderly and controlled manner. In cancer, the cells multiply without proper control. Cancer of the ovaries ('ovarian cancer') is one of the most common cancers in women; in England and Wales, about 6000 cases of ovarian cancer are diagnosed each year.

Women who have ovarian cancer usually have surgery to remove as much of the tumour (the mass of cancer cells) as possible and then have 'chemotherapy', which means treatment with drugs that destroy cancer cells. The type of drug used depends on the stage of the disease.

Paclitaxel is one of a group of anticancer ('cytotoxic') drugs known as taxanes. Cytotoxic drugs are used to destroy cancer cells.

The most common initial ('first-line') chemotherapy treatment for ovarian cancer is a combination of a platinum-

What is ovarian cancer?

What is paclitaxel?

containing drug (cisplatin or carboplatin) and another drug known as paclitaxel (Taxol). It's estimated that currently more than 7 out of 10 women with ovarian cancer receive this initial treatment.

NICE carried out an appraisal of the use of paclitaxel for the treatment of ovarian cancer and issued recommendations in May 2000. It has now carried out a review of that guidance, taking into account both the evidence that was available for the previous appraisal and new evidence. In particular, it has considered the full results of a clinical study that were not available for the previous appraisal.

NICE has made the following recommendations about the use of paclitaxel to treat ovarian cancer.

- Either paclitaxel in combination with a platinum-based therapy (cisplatin or carboplatin) or platinum-based treatment alone should be offered for initial (first-line) chemotherapy (usually after surgery). The choice of

What has NICE recommended ?

treatment should be made after the woman and her doctor have discussed the potential risks and benefits of the treatment options available. This discussion should cover the side effects of the treatments, the stage of the woman's disease, how much of the tumour has been removed by surgery, and how much the disease has affected the woman's overall health and function.

- If the cancer returns, further courses of the first-line chemotherapy used previously should be considered, provided that the response to the previous treatment was adequate in terms of how well it worked and how long it lasted. (This is called 're-challenge therapy'.) When there is not an adequate response to the chosen first-line treatment, different treatment options should be considered as part of second-line chemotherapy.
- Paclitaxel is not recommended as second-line (or subsequent) therapy

for a woman with ovarian cancer who has been treated with paclitaxel as part of her first-line treatment. For a woman who has not received paclitaxel as part of first-line treatment, it should be considered as one option alongside other drugs licensed for second-line treatment of ovarian cancer.

- When chemotherapy is used to treat ovarian cancer, the treatment should be supervised by a doctor who specialises in the treatment of ovarian cancer.

Are these recommendations different from the ones NICE issued previously?

Yes. When all the evidence now available is considered together, it suggests that there is no clear advantage of the combination of paclitaxel and a platinum-based drug over a platinum-based drug on its own for first-line treatment of ovarian cancer. So NICE now recommends that both treatments should be offered as options and that the choice of treatment should be made after the woman has discussed the potential risks and benefits with her doctor. The new guidance emphasises that women should be involved in making choices about their treatment.

The new guidance also makes clear the distinction between re-challenge therapy and second-line treatment. There has been no significant change in the guidance on the use of paclitaxel in the second-line (or subsequent) treatment.

What should I do?

If you or someone you care for has ovarian cancer, you should discuss this guidance with your hospital doctor at your next appointment.

Will NICE review its Guidance?

Yes. The review of this guidance will begin in July 2003. The review will cover the use of paclitaxel and two other drugs – topotecan and pegylated liposomal doxorubicin hydrochloride (PLDH) – in the treatment of ovarian cancer.

Further information

The NICE website (www.nice.org.uk) has further information on NICE and the full guidance on the use of paclitaxel in the treatment of advanced ovarian cancer that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0185. The recommendations NICE has made on the use of topotecan and PLDH in the treatment of ovarian cancer are also available from the