

Monthly briefings are produced in order to help members of the media and other interested groups understand the work and advice of the Scottish Medicines Consortium. The full advice for each drug that we have assessed can be found at [www.scottishmedicines.org](http://www.scottishmedicines.org).

SMC has this month accepted the following drugs for use within NHSScotland.

## tenofovir disoproxil 245mg film-coated tablet (Viread®)

SMC has accepted tenofovir disoproxil for the treatment of chronic hepatitis B in adults with compensated liver disease.

- Hepatitis B is a virus that is transmitted by infected blood and body fluids. It can cause an infection with flu-like symptoms, but usually resolves without treatment. However, in some cases the virus can cause chronic illness that lasts for months and potentially for life, with symptoms that come and go. Hepatitis B can cause liver disease in which the liver cells are damaged by the hepatitis infection but the liver continues to function normally (known as compensated liver disease). Chronic hepatitis B infection can also cause damage which affects liver function (a condition known as cirrhosis) and liver cancer.
- If chronic illness develops, antiviral treatment may be used to prevent cirrhosis and/or liver cancer. Tenofovir disoproxil is a new antiviral drug that stops the hepatitis B virus from increasing. It can lessen or stop the symptoms of chronic liver disease (a phase called remission). It is given as a tablet.
- Studies have shown that tenofovir disoproxil reduced the amount of virus to a low target level in more patients than did a similar drug.
- Side effects of tenofovir disoproxil are similar to those of a comparator antiviral drug. Before starting and during treatment with tenofovir disoproxil, patients should be monitored to make sure their kidneys are working properly.
- SMC accepted tenofovir disoproxil because it is more effective and cheaper than some similar drugs for this illness.

## About SMC

The purpose of the Scottish Medicines Consortium (SMC) is to accept for use those newly licensed drugs that clearly represent good value for money to NHSScotland.

SMC analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price.

Because the NHS has limited resources, SMC works to make sure that those drugs which represent good value for money are accepted for routine use as quickly as possible so that they can benefit patients.

The Consortium is made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry, the public and the Scottish Government.

### ■ Contact Details

If you are interested in the work of SMC you can visit our website at:

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)

or contact us at:

Scottish Medicines Consortium  
Delta House (8th floor)  
50 West Nile Street  
Glasgow  
G1 2NP

[smcsecretariat@nhshealthquality.org](mailto:smcsecretariat@nhshealthquality.org)

### ■ Media Contact

Members of the media should contact **Stephen Ferguson** on 07779 329 689

## docetaxel 20mg and 80mg concentrate and solvent for solution for infusion (Taxotere®)

SMC has accepted docetaxel for the induction treatment of patients with locally advanced squamous cell carcinoma (a type of cancer) of the head and neck in combination with cisplatin and 5-fluorouracil, in patients whose cancer can be removed surgically. Its use is restricted to patients in whom induction chemotherapy is appropriate.

- Cancer is the term given to a group of abnormal cells which have clumped together and grow to form a tumour. Cancer can occur in many regions of the head and neck area including the lips, mouth, nose, ears and eyes.
- Docetaxel is an anticancer therapy which damages the supporting structure of the cancer cells and stops their growth. It is given by a drip as induction chemotherapy (initial treatment before surgery or radiotherapy).
- Studies have shown that patients treated with docetaxel, given along with two other drugs called cisplatin and 5-fluorouracil, survived for longer than patients treated with cisplatin and 5-fluorouracil alone.
- No new safety concerns were noted with docetaxel in this group of patients.
- SMC accepted docetaxel for restricted use because it has benefits in these patients and offers good value for money.
- SMC has already accepted docetaxel for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck in patients whose cancer cannot be removed surgically. This now extends that advice to patients who are eligible for surgery.

## fesoterodine fumarate 4mg and 8mg prolonged-release tablets (Toviaz®)

SMC has accepted fesoterodine fumarate prolonged-release tablets for the treatment of symptoms in patients with overactive bladder syndrome. It is restricted to second-line use (when another treatment has already been tried and has not worked or has caused side effects).

- Overactive bladder syndrome is when the bladder contracts suddenly without the patient having control, and when the bladder is not full. It is a common condition and usually no cause can be found. Symptoms include increased urinary frequency (need to pass urine often), urgency (sudden urge to pass urine) and urgency incontinence (sudden lack of control resulting in urine leaking before the person can get to the toilet).
- Fesoterodine fumarate is a medicine to treat the symptoms of overactive bladder syndrome. It is given as a prolonged-release tablet which means that the medicine is released slowly from the tablet and can be taken once daily. Fesoterodine fumarate works by causing the bladder muscles to relax, which helps prevent unwanted urination.

- Studies have shown that fesoterodine fumarate caused a modest reduction in urinary frequency and the effect was similar to that of a comparator medicine.
- The side effects of fesoterodine fumarate are similar to those of other related medicines.
- SMC accepted fesoterodine fumarate as a second-line treatment because it is effective and costs about the same as some medicines currently used as second-line treatments. Other less expensive medicines are available and would normally be tried first.

SMC decided that the following drugs are not value for money for NHSScotland.

## sorafenib 200mg (Nexavar<sup>®</sup>)

SMC did not recommend sorafenib for the treatment of patients with hepatocellular carcinoma (cancer of the cells in the liver).

- Cancer is the term given to a group of abnormal cells which have clumped together and grow to form a tumour. Hepatocellular carcinoma is a type of cancer which starts in the cells of the liver.
- Sorafenib is an anticancer medicine for use in patients with liver cancer. It works by blocking cancer cell signals and reducing the formation of new blood vessels that provide oxygen to the cancer cells, preventing the cancer cells from growing. Sorafenib is taken as a tablet.
- A study has shown that patients treated with sorafenib survived for up to 12 weeks longer than patients treated with placebo (a dummy treatment containing no active drug). There was no difference in the time it took for symptoms to progress in sorafenib-treated patients compared with placebo-treated patients.
- The most common side effects of sorafenib in patients with liver cancer were diarrhoea, hand-foot syndrome (burning pain in the hands and feet), fatigue and hair loss.
- SMC decided not to accept sorafenib for use within NHSScotland because, when the balance of costs and benefits of the treatment was considered, it did not offer good value for money.

## paricalcitol 5 micrograms/ml and 10 micrograms/ml solution for injection and 1, 2 and 4 micrograms capsules (Zemplar<sup>®</sup>)

SMC did not recommend paricalcitol for the prevention and treatment of secondary hyperparathyroidism in patients with kidney disease undergoing dialysis.

- Parathyroid hormone is a natural substance made by the body. In patients with long-term kidney disease, the levels of parathyroid hormone can become too high. This is called hyperparathyroidism and it can cause serious problems such as bone disorders. The condition involves a decrease in vitamin D levels.
- Paricalcitol is a medicine that is closely related to vitamin D which helps control parathyroid hormone and other minerals (eg calcium) that are needed to build and keep strong bones. It is a medicine that can be given by injection into a vein and is also available as a capsule to be taken by mouth.
- A study has shown that patients treated with paricalcitol injections had a reduction in levels of parathyroid hormone that was similar to that seen in patients treated with another form of vitamin D. No studies directly compared paricalcitol capsules with other medicines used to treat hyperparathyroidism .
- The side effects of paricalcitol are similar to those of other vitamin D preparations.
- SMC decided not to accept paricalcitol injection or capsules because it is more expensive than other similar drugs and the case submitted by the manufacturer failed to show that it was good value for money.

## ferric carboxymaltose, 100mg/2ml and 500mg/10ml solution for injection/infusion (Ferinject<sup>®</sup>)

SMC did not recommend Ferinject<sup>®</sup> for the treatment of iron deficiency when oral preparations fail to work or cannot be used.

- Anaemia is a condition in which the blood does not supply the body's tissues with enough oxygen. The most common form of the condition is iron deficiency anaemia. This is where the body lacks the amount of iron needed to make enough red blood cells.
- Generally, tablets are given to replace the iron. Sometimes, iron given in this way cannot be absorbed by the body (for example, if the patient is ill or can't swallow). Ferinject<sup>®</sup> is an iron replacement therapy which is given by injection to patients if iron tablets are not suitable.
- Studies have shown that Ferinject<sup>®</sup> worked at least as well as other iron replacement therapies. However, only one study compared Ferinject<sup>®</sup> with another iron injection and there were not enough patients in the study to show which drug worked best.
- Patients who were given Ferinject<sup>®</sup> had less nausea, constipation and diarrhoea but more skin

problems and headaches than patients who were given iron replacement tablets.

- SMC decided not to accept Ferinject<sup>®</sup> for use within NHSScotland because the economic case submitted by the manufacturer failed to show that the drug would be good value for money.

For drugs that have not been accepted by SMC, all NHS boards have procedures in place to consider individual requests when a doctor feels the drug would be right for a particular patient. SMC has told the manufacturers why the drug was not accepted and would be pleased to receive any resubmission.

For further information and to view the complete advice for the drugs listed above, visit our website at:

[www.scottishmedicines.org.uk](http://www.scottishmedicines.org.uk)